IMPACT OF SITE OF VENOUS REFLUX IN HEALING OF RECALCITRANT LEG ULCERS

AN OBSERVATIONAL STUDY

Dissertation
Submitted in partial fulfillment of the regulations of

M.S. DEGREE EXAMINATION

BRANCH I GENERAL SURGERY

Department of General Surgery

GOVT. STANLEY MEDICAL COLLEGE AND HOSPITAL

CHENNAI - 600001

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

CHENNAI

APRIL 2014

CERTIFICATE

This is to certify that this dissertation titled

"IMPACT OF SITE OF VENOUS REFLUX IN HEALING OF RECALCITRANT LEG ULCERS"

AN OBSERVATIONAL STUDY

is the bonafide work done by **Dr.MEENAAKSHI.N,** Post Graduate student (2011 – 2014) in the Department of General Surgery, Government Stanley Medical College and Hospital, Chennai under my direct guidance and supervision, in partial fulfillment of the regulations of The Tamil Nadu Dr. M.G.R Medical University, Chennai for the award of M.S., Degree (General Surgery) Branch - I, Examination to be held in April 2014.

Prof. Dr.T.S.JAYAHREE, M.S.,
Professor of Surgery,
Dept. of General Surgery,
Stanley Medical College,
Chennai-600001.

Prof.Dr.K. KAMARAJ, M.S.,
Professor and Head of surgery,
Dept. of General Surgery,
Stanley Medical College,
Chennai-600001.

PROF. S. GEETHA LAKSHMI, M.D., PhD,
The Dean**,**
Stanley Medical College,
Chennai-600001.

DECLARATION

I, **Dr.MEENAAKSHI.N** solemnly declare that this dissertation title "**IMPACT OF SITE OF VENOUS REFLUX IN HEALING OF RECALCITRANT LEG ULCERS"**is a bonafide work done by me in the Department of General Surgery and Department of Vascular Surgery Government Stanley Medical College and Hospital, Chennai under the guidance and supervision of my unit chief.

Prof.Dr.T.S.JAYASHREE, M.S.,
Professor of Surgery

This dissertation is submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the university regulations for the award of M.S., Degree (General Surgery) Branch - I, Examination to be held in April 2014.

Place: Chennai.
Date: December 2013. **Dr.MEENAAKSHI.N**

ACKNOWLEDGEMENT

I am grateful to **Prof.Dr. S. Geethalakshmi,** Dean, Govt. Stanley Medical College for permitting me to conduct the study and use the resources of the College.

My sincere thanks to **Prof.Dr. K. Kamaraj,** Professor and HOD, Department of General Surgery, for his valuable guidance throughout the study.

I am highly indebted to my guide **Prof.Dr.T.S.Jayashree**, Professor of Surgery for her constant help, inspiration and valuable advice in preparing this dissertation.

I express my deepest sense of thankfulness to my Assistant Professors **Dr.D.Dorai, Dr.T.Chitra, Dr.Jeyachander** for their valuable inputs and constant encouragement without which this dissertation could not have been completed.

I consider it a privilege to have done this study under the supervision of my beloved former Professor and Head of the Department **Prof. P. Darwin**, who has been a source of constant inspiration and encouragement to accomplish this work.

I express my sincere gratitude to my mentor **Prof.Dr.Rajkumar,** former Head of Department of Vascular Surgery.

I would like to thank **Prof. Dr.S.R.Subramaniyam**, Professor and Head. Department of Vascular surgery and Prof.**Dr.Amarnath**, Professor and HOD in Radiology without whose help this dissertation would not be possible.

I am particularly thankful to my fellow postgraduate colleagues Dr.Satyanarayanan.M and Dr.Viswakumar.P for their valuable support in the time of need throughout this study.

I would be failing in my duty without acknowledging the contribution of my seniors Dr.Abinaya.R.C, Dr.Baskar.A.R, Dr.Dalton Jebaraj, and my friends Dr.Manivanan, Dr.Rajkamal, Dr.Vinod, Dr.Aarthy, Dr.Kodieswaran and Dr. Prasanna.G, in helping me in completing this dissertation

It is my earnest duty to thank my Parents, Husband and siblings without whom accomplishing this task would have been impossible.

I am extremely thankful to my patients who consented and participated to make this study possible.

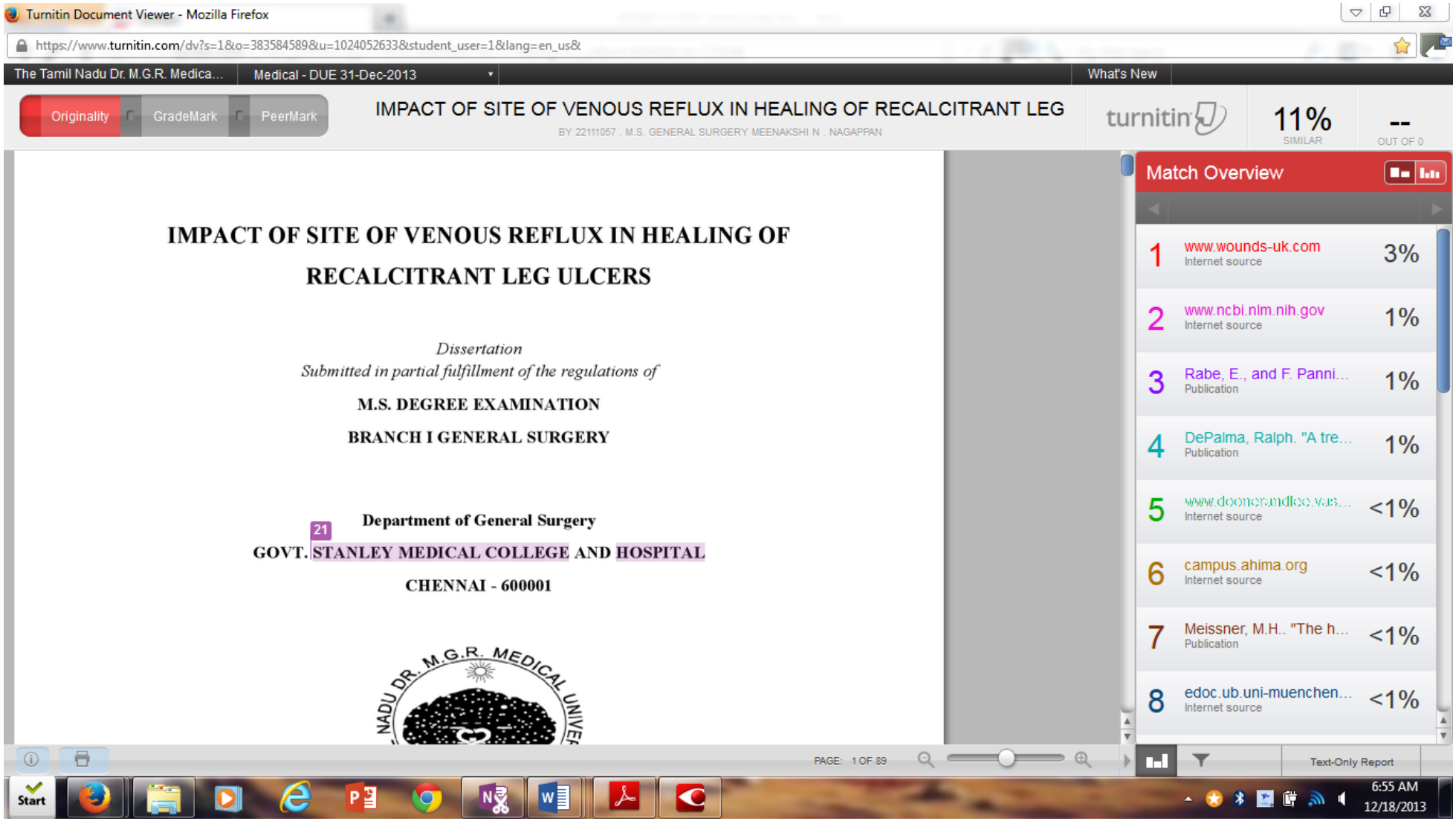

Turnitin Document Viewer - Mozilla Firefox
https://www.turnitin.com/dv?s=1&o=383584589&u=1024052633&student_user=1&lang=en_us&
The Tamil Nadu Dr. M.G.R. Medica...
Medical - DUE 31-Dec-2013
What's New
Originality
GradeMark
PeerMark
IMPACT OF SITE OF VENOUS REFLUX IN HEALING OF RECALCITRANT LEG
BY 22111057 . M.S. GENERAL SURGERY MEENAKSHI N . NAGAPPAN
turnitin
11%
SIMILAR
--
OUT OF 0
IMPACT OF SITE OF VENOUS REFLUX IN HEALING OF
RECALCITRANT LEG ULCERS
Dissertation
Submitted in partial fulfillment of the regulations of
M.S. DEGREE EXAMINATION
BRANCH I GENERAL SURGERY
Department of General Surgery
GOVT. STANLEY MEDICAL COLLEGE AND HOSPITAL
CHENNAI - 600001
Match Overview
1 www.wounds-uk.com Internet source 3%
2 www.ncbi.nlm.nih.gov Internet source 1%
3 Rabe, E., and F. Panni... Publication 1%
4 DePalma, Ralph. "A tre... Publication 1%
5 Internet source <1%
6 campus.ahima.org Internet source <1%
7 Meissner, M.H.. "The h... Publication <1%
8 edoc.ub.uni-muenchen... Internet source <1%
PAGE: 1 OF 89
Text-Only Report
Start
6:55 AM
12/18/2013

TABLE OF CONTENTS

IMPACT OF SITE OF VENOUS REFLUX IN HEALING OF RECALCITRANT LEG ULCERS

AN OBSERVATIONAL STUDY

Key words:Venous ulcer, Reflux disease, chronic venous insufficieny

BACKGROUND:

Venous ulcers (ulcus **cruris**) are wounds in legs due to malfunctioning of venous valves. Among leg ulcers they are the major contributors nearly 79-83%. Approximately 24-30% of patients are of the age of 42-45 and 60-70% are between age of 60-64.They are otherwise healthy individuals losing their productive period of living because of these ulcers.

The pathophysiology of venous insufficiency may be due to valvular reflux, destroyed valves, or perforator paucity. Leucocytes cause inflammation, and later the platelets adhere form a pericapillary cuff of fibrin, leading to tissue hypoxia, cell death and ulceration.

More common cause 75% of venous ulcer being superficial, perforator or deep venous reflux rather than obstruction which is a less frequent cause 1-3%.Trauma are in 23% of cases, and congenital anomaly in 1-2%.

Color Duplex scan is the investigation of choice, which gives information about patency and reflux.

The treatment options for venous problems are conservatively by limb elevation and a compression bandage. Medically managed with drugs like pentoxifylline, aspirin and micronized flavinoids. Once the patient does not respond to conservative management, surgical intervention becomes mandatory, both for the underlying cause and a cover for ulcer should be instituted. The various surgical option available for superficial venous system reflux are ligation and stripping of superficial varicose veins, endoscopic subfascial perforator ligation, foam sclerotherapy, endovenous laser or radiofrequency ablation. The medical cost incurred towards treating these is much their financial burden of lost work is huge for the patient and the government as these venous ulcers are either neglected or managed inappropriately.

METHODS:

Between December 2012 to November 2013 , the patients who had presented to the general surgery and vascular surgery outpatient department of inclusion criteria were admitted evaluated using duplex , ulcer was documented on visitrak treated and periodically observed .

RESULTS

In this study we observed majority of patients 69. 6 % belonged to age group of 40-59. Men 92 % were affected more. Right lower 48% limb slightly predominates left 40 %. The patients have recalcitrant ulcer ranging from 12- 38 weeks duration peeks between 20-22 weeks. On duplex the SFJ reflux 56.5 %

dominated followed by the SFJ along with perforators 28.9 %. Most common anatomic presentation was incompetence in the SFJ (grade II reflux 69. 7% dominates over grade III 30.3%).Among perforator's leg perforators are most common site. CEAP 4 heals earlier then its counterparts approximately by 12 weeks followed by CEAP 5 which takes 22 weeks and then CEAP 6 which takes 28-30 weeks' time. Finally The SFJ are the first to heal majority heal by 16 weeks .Perforators as pathology took longer duration to heal 28 weeks. When all three the SFJ, SPJ and Perforator are present it takes the maximum time of around 30 weeks to heal.

CONCLUSION: This study clearly suggest that as far as pigmentation and ulceration are concerned the underlying pathophysiology and **reflux** in the **SAPHENOFEMORAL JUNCTION and PERFORATOR** are more harmful and if left untreated take longer time to heal. They are statistically significant with the p value being **0.029 and .007** for saphenofemoral junction and perforator reflux respectively. As ever, the reality is more complicated as there is much still to be discovered as in this study the sample size was small and more number of cases will be needed for precious conclusions. In the meantime a working knowledge of the underlying process can help these ulcer patients heal faster

INTRODUCTION

Venous ulcers (**ulcus cruris**) are wounds in legs due to malfunctioning of venous valves. Venous ulcers are most severe debilitating sequelae of chronic venous insufficiency (CVI). Among leg ulcers they are the major contributors nearly 79- 83%. Approximately 24-30% of patients are of the age of 42-45 and 60-70% are between age of 60-64.They are otherwise healthy individuals losing their productive period of living because of these ulcers.

The pathophysiology of venous insufficiency may be due to valvular reflux, destroyed valves, or perforator paucity. Following this there are a series of reactions which take place if left untreated, the leucocytes cause inflammation, and later the platelets adhere form a pericapillary cuff of fibrin, leading to tissue hypoxia, cell death and ulceration.

More common cause 75% of venous ulcer being superficial, perforator or deep venous reflux rather than obstruction which is a less frequent cause 1-3%.Trauma are in 23% of cases, and congenital anomaly in 1-2%.

Color Duplex scan is the investigation of choice , which gives information about patency and reflux. Whether there is any compression proximally or distally.

The treatment options for venous problems are conservatively by elevating the affected limb and giving a compression bandage. Medical

management is usually with drugs like pentoxifylline , aspirin and micronized flavinoids.

Once the patient has least response to conservative line of management and ulcer persist, surgical intervention becomes mandatory, both the underlying cause and a cover for ulcer should be instituted. The various surgical option available for superficial venous system reflux are ligation and stripping of superficial varicose veins, endoscopic subfascial perforator ligation, foam sclerotherapy ,endovenous laser or radiofrequency ablation. For deep venous reflux the incompetent valves if possible can be repaired, transplantation or transposition of segment of competent vein with normal valves be replaced in the thrombotic or destroyed segment.

The medical cost incurred towards treating these is much their financial burden of lost work is huge for the patient and the government as these venous ulcers are either neglected or managed inappropriately.

AIM OF STUDY

There has been various reports on distribution of venous reflux among venous ulcer patients, but the exact contribution of each system has not been arrived at a consensus. This Study will analyze with the aid of duplex the saphenous venous reflux which may be secondary to saphenofemoral incompetence or saphenopopliteal incompetence, perforator incompetence and deep venous insufficiency.

This paper highlights the importance of achieving accurate diagnosis and to assess whether, a difference in venous reflux pattern can predict the healing of a chronic venous leg ulcer after instituting effective treatment.

REVIEW OF LITERATURE

HISTORICAL BACKGROUND

EBER PAPYRUS (1550 BC) AND BY HIPPOCRATES:

Venous problems have been spoken of since antiquity, in Bible.

VESALIUS:

The veins anatomy was described by him.

HIPPOCRATES

"It was better not to stand in case of an ulcer on the leg,"

MARIANUS FELT

"Standing too much before kings " leads to ulcer

Athens in Greece has a stone votive dedicating to his physician, which shows varicosities in long saphenous vein in their National museum.

"Cut skin, expose varix, insert probe under it … pull out varix"was followed by the Arabs from BC 400

DE HUMANI CORPORIS FABRICA (1543)

First discovered that veins have valves.

PARE'S (16th Century)

Described the compression bandaging technique from foot to mid-thigh

ABRICIUS (HIERONYMUS FABRICIUS AB AQUAPENDENTE) 1603

described the venous valves are mainly responsible to prevent reflux

BRODIE (1846)

First to described visible superficial venous reflux.

GAY (1867)

Coined "venous ulcer"

TRENDELENBURG

First described saphenofemoral junction ligation .

HOMANS(1916)

Explained pathophysiology, etiology, and treatment of varicose veins ,

LINTON (1938)

First explained the technique of perforator interruption

LINTON (1953)

Described that chronic venous ulceration and dermatitis, caused by ambulatory venous hypertension.

EMBRYOLOGY AND ANATOMY

The limbs primitive vascular channels first appear during third week of gestation

Woolard in 1922 described that the vascular system undergoes differentiation through multiple stages during development

STAGE 1: Only a capillary network is present- Undifferentiated stage

STAGE 2: Large plexiform structures appear- Retiform stage

STAGE 3 In the 3rd week of gestation large arteries and veins - *Maturation* stage .

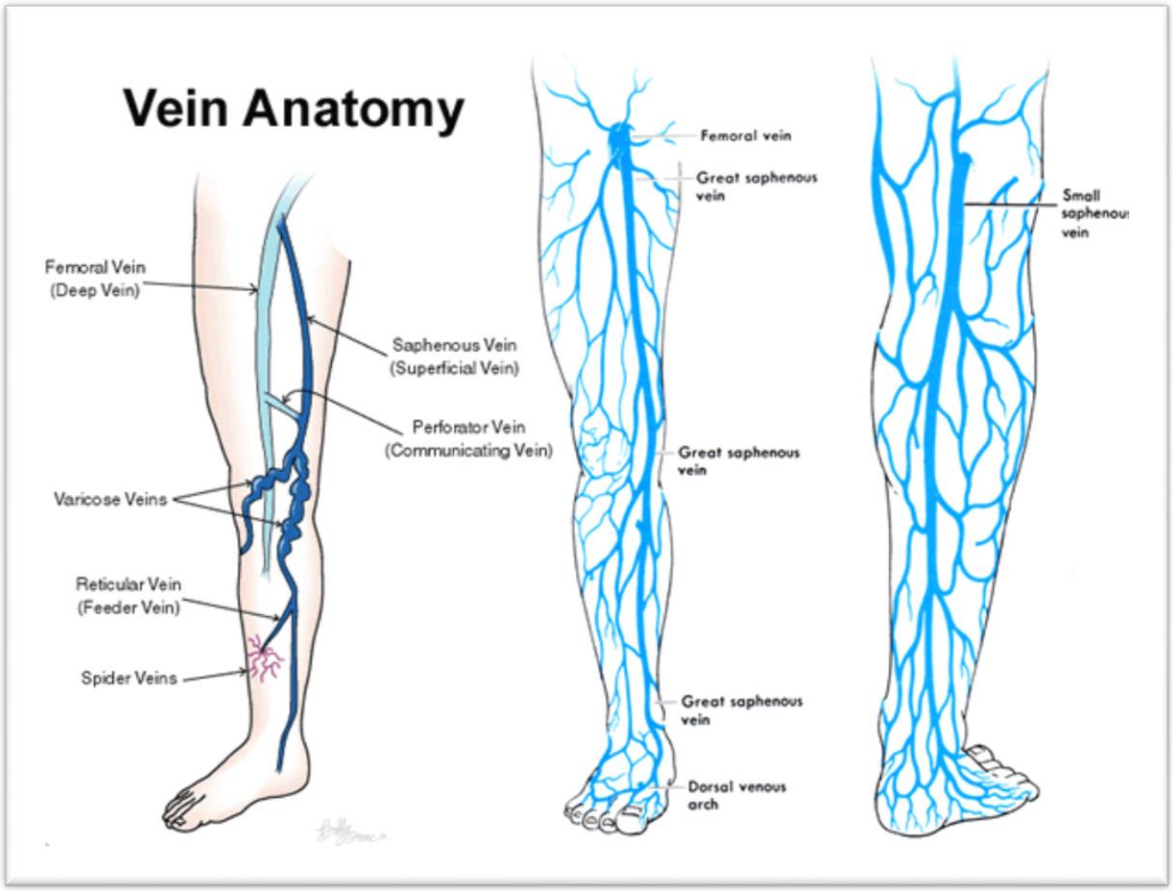
Keratinocytes secrete VEGF . The Venous system appears first bilaterally. The right side vasculature form the superior and inferior vena

cavae whereas the left vessels regress. These patterns of development only are seen as anatomic variants among few individuals.

From the aorta arises multiple capillary network which in turn gives rise to various segmental branches these later form the vasculature in the limbs.

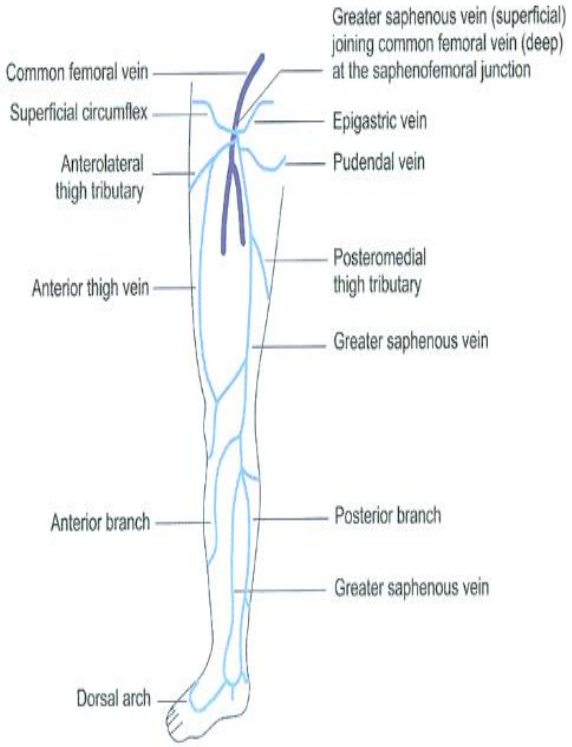
The axial or *central artery* is present for each limb since the time the limbs extends from the body. New vascular sprouts arise in limbs as they grow from these capillary networks and marginal sinus. The marginal sinuses drain blood

initially into the superficial venous plexuses , from here blood gets shunted into deep veins along the major arteries. around the sixth month of gestation most of the valves are formed in the limb veins. Gillot described that major nerves induce the development of veins like the femoral, sciatic and posterior femoral cutaneous nerves. During development most of the embryonic veins regress, if they persist (sciatic and lateral marginal vein) they are mostly as venous malformations.



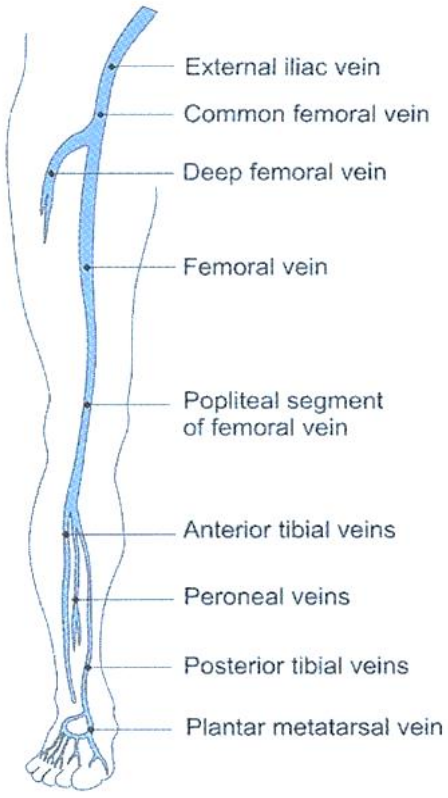
SUPERFICIAL VEINS

The superficial veins are superficial to the deep fascia they act as conduits and take blood from surface to deep veins via perforating veins. There are two identifiable systems with interconnection .The long saphenous vein drains the inner leg upto the groin, the other short saphenous vein which drains the back of calf to popliteal vein behind knee. When these veins dilates they regulate temperature. When there is gross dilatation it leads to development of varicose veins. Both systems have valves throughout the length and become numerous in lower leg. The superficial veins of the lower limb are as illustrated



DEEP VEINS

The deep veins are deep to deep fascia. Some of these veins act as conduits while others act as venous sinuses within muscles and form an part of the pumping mechanism. The picture illustrates deep veins of lower limb

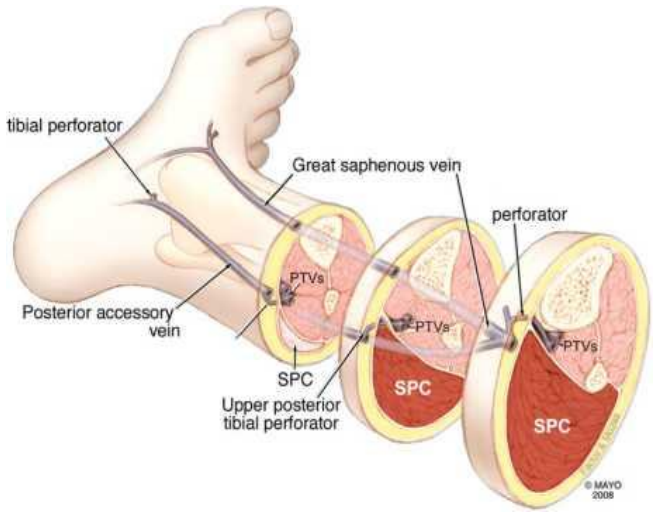


PERFORATING VEINS

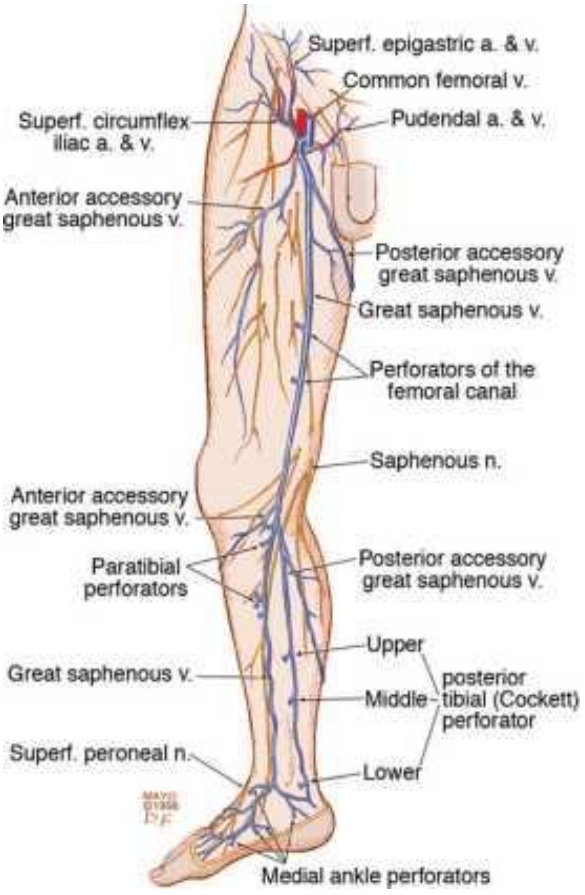
The veins which connect superficial and deep veins are called perforators. They connect the long saphenous and common femoral vein, the short saphenous and popliteal

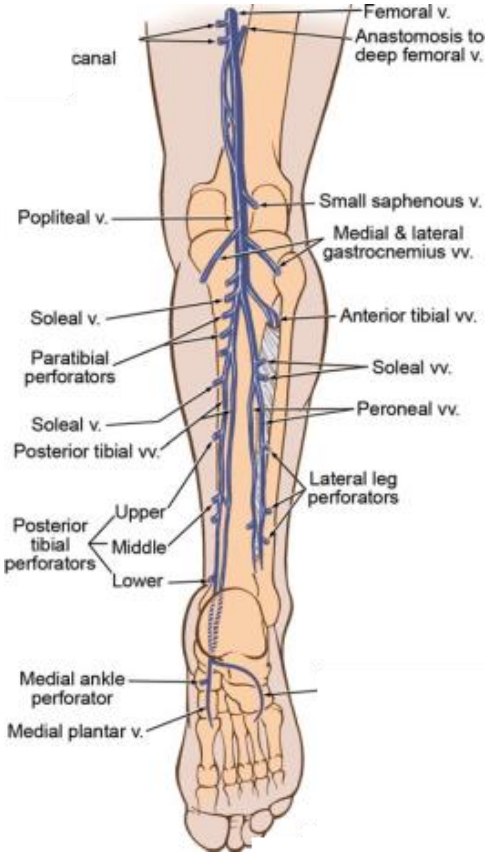
vein. It is also estimated that over 60 other sites of communication are present. The perforating veins will allow flow from superficial to deep system only. In some perforating veins, valves are identifiable, in others inward flow regulates while muscle contracts.

This figure shows the 3-D view for leg perforators connecting the superficial and deep venous system



<u>These two figure illustrate the perforators on the medial and posterior aspect of the lower limb respectively</u>





Structure

Veins return blood to heart against the force of gravity through a complex pumping mechanism . The veins are designed specifically so that they allow blood flow only in one direction. Venous reflux is prevented by the presence of numerous valves in them. The Vein wall supports these valves and their integrity has sufficient strength to prevent dilatation. When human beings stand these veins distend and on lying flat they automatically collapse.

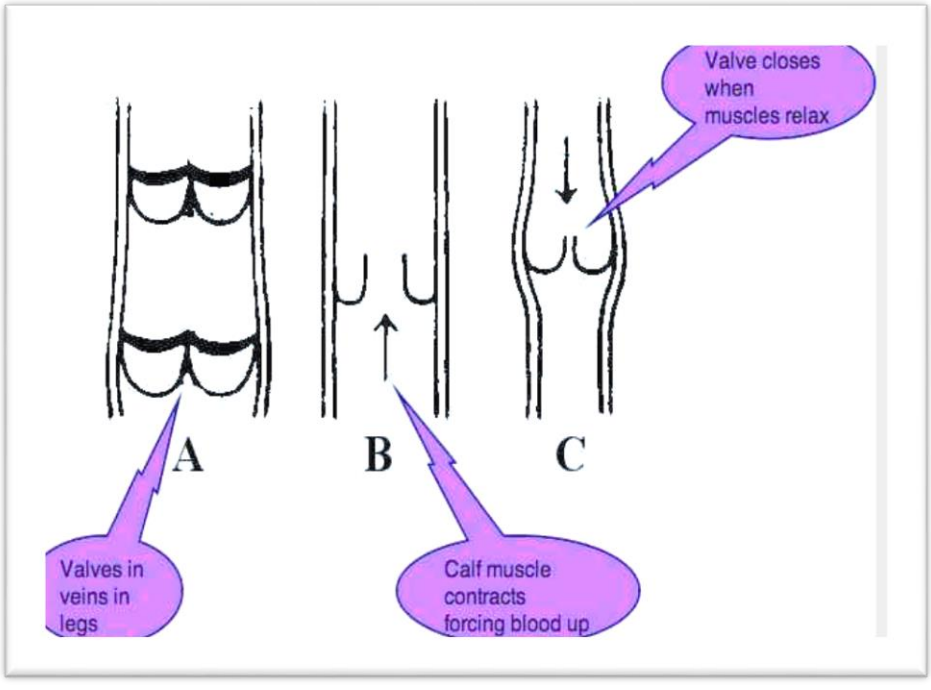
The lining endothelium of the vein provides a non-thrombo-geneic surface If there are long periods of stasis, hypoxia or white cell interaction the endothelial layer may be damaged , the veins themselves use a protective mechanism by producing fibrinolysins which dissolves clot.

VEINS AS PUMPING CHAMBERS

Venous pumps are present in the foot, calf, and thigh. On walking there is muscle contraction, which compresses the veins . The valves will ensure that the blood is moved towards heart and it is an important mechanism in assisting venous return.when theres is a damage to joints, muscles, or valves this mechanism is interfered .

When the venous pump is impaired the normal venous return does not happen; so the venous pressure remains the same during exercise instead of falling.

when there is venous obstruction, during exercise venous pressure rises. The resulting pathophysiological consequences is the development of skin changes followed by ulceration.



COLLATERAL FLOW

Collateral veins develop when regular veins become obstructed; when there is occlusion of femoral vein it results in dilatation of superficial veins thereby providing an alternative drainage system. Those who develop occlusion at the iliac vein have dilated superficial veins in the groin.

VENOUS PHYSIOLOGY

Four-fifths of circulating blood is in the veins. The veins by regulating the capacity of circulation and contraction of main veins play an important role during blood loss. Paralysis of veins results in venous pooling which can lead to postural hypotension and patient faints. The arterial pressure across the capillary bed , muscle venous pump and gravity effect facilitates the blood flow through veins. The position of the patient determines the pressure in veins , when the patient is lying down and their foot are elevated slightly the pressure in the veins is zero. When the patient is standing the weight of column of blood from foot to heart determines the pressure in veins. This may be 100 mm Hg. when he exercises the pressure drops down to 20 mm of Hg by the muscle pumps and joints. When there is any damage to the vein muscle pump or joint no pressure

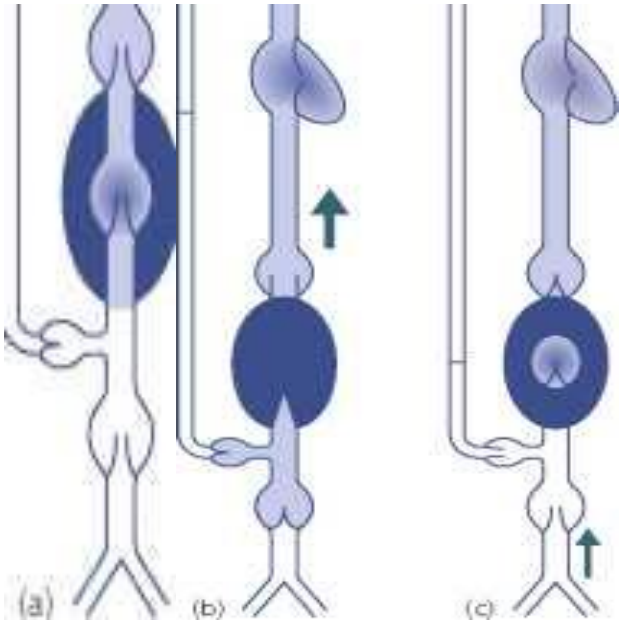
change is observed. a thrombus in femoral or iliac vein will rise the pressure during exercise because there is venous outflow obstruction

HEMODYNAMICS OF CHRONIC VENOUS INSUFFICIENCY

PERIPHERAL MUSCLE PUMP MECHANISM

The muscle pump pushes the blood against gravity while the

valves present internally efficiently prevent blood from flowing in retrograde fashion. This mechanism functions well in normal human beings



Drawing illustrating "The muscle pump." (a) resting state (b) muscle contraction state (c) muscle relaxation state

There is back flow of blood when the pressure volume relationship is not maintained, slowly the veins dilate giving rise to varicosities in the long run, the blood stagnates it induces secondary changes in the skin causing lipodermatosclerosis followed by ulcer.

PATHOPHYSIOLOGY of VENOUS ULCER

Inflammatory reaction by leukocytes which act on endothelium and microcirculation of veins. The functions of these cells are altered dysregulating the cellular elements like fibroblast and keratinocytes . The

MMPs are overexpressed and they influence the ECM creating fluid in the wound which delays healing like …

It is evident that varicose vein formation has a genetic background also.

1. Leukocyte initiate inflammatory events. Advanced CVI stages there is protracted healing of venous ulcers because of the dysfunctional leukocytes

2. Macrophage population dominate the postcapillary venules thereby also having a part in ulcer formation

3. In CVI patients the neutrophils get activated which in turn causes macrophage sequestration leading to inflammation.

4. They have decreased expression of mitogenic receptors

5. The venous ulcer wound fluid directly down regulates ERK

6. Integrin receptor in wound bed hinders with re-epithelialization

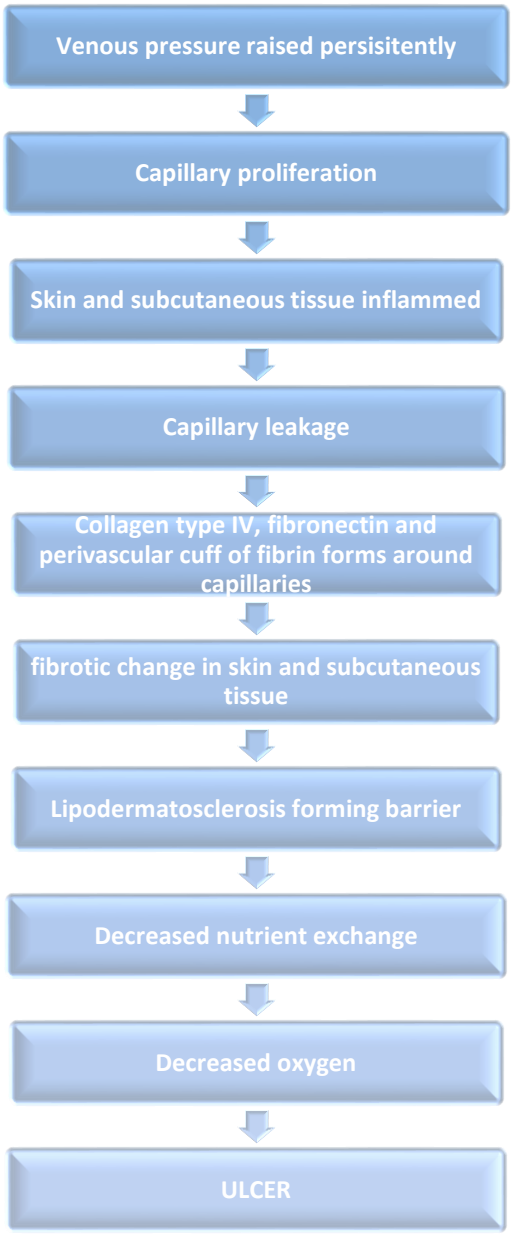
7.The inhibitory cytokines and MMPs in fluid have a role in conversion from lipodermatosclerosis stage to active ulcer

8. MMPs degradative properties are a reason for delayed healing

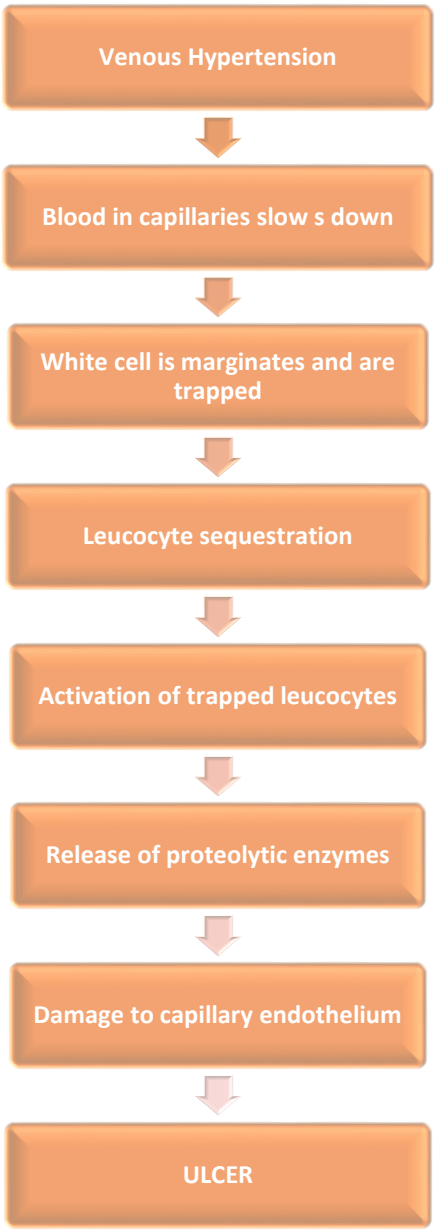
9. The collagenase and gelatinase in keratinocytes and endothelial cells aids in

10. EMMPRIN is expressed in venous ulcer, which activates leukocytes.

BROWSE FIBRIN CUFF THEORY



WHITE CELL TRAPPING THEORY DORMANDY



To conclude it is apparent that venous ulcer involves systemic and local processes. So targeting only one system may or may not cause a clinical change and probably multimodality management has to be instituted.

RISK FACTORS FOR DEVELOPMENT OF VARICOSE VEINS

Age > 50 years

Female sex

Occupation which demands prolonged standing

Hormones - progesterone

Computer professionals – prolonged sitting – thrombosis

Recent long flight travel.

SYMPTOMS OF VENOUS INSUFFICIENCY

1. Asymptomatic

2. Cosmetic problems

3. Aching

4. Heaviness and cramps

5. Itching

6. Venous claudication

7. Ankle swelling towards end of the day

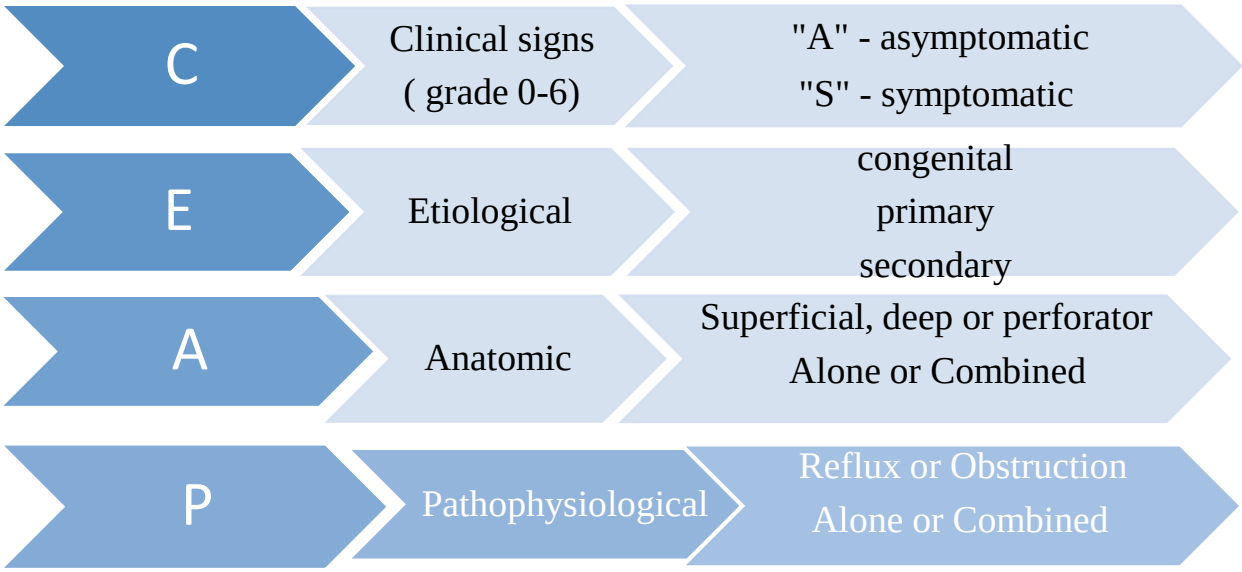
8. Pigmentation on the medial aspect

9. Eczema

10. Ulcer

CLINICAL SEVERITY CLASSIFICATION

SCORING SYSTEM- CEAP- VENOUS DISEASE STARTIFICATION



The CEAP system can be further detailed as follows

The Clinical classification has 7 classes from class 0 to class 6

CLINICALCLASSIFICATION CLASS 0-6	
CLASS 0	**No visible venous disease**
CLASS 1	**Telangiectasia, Reticular veins, Malleolar flare**
CLASS 2	**Varicose veins**
CLASS 3	**Edema but no skin changes**
CLASS 4	**Pigmentation, eczema, Lipodermatoslerosis**
CLASS 5	**Above changes with healed ulcer**
CLASS 6	**Skin changes with active ulcer**
Further classified into A or S like $C_{0\text{-}6\ A}$ / $C_{0\text{-}6S}$ A if asymptomatic, S if patient has ache, pain, tightness or skin irritation	

The Etiological classification has 3 categories

Etiologic Classification (E_C, E_P, or E_S)	
Congenital (E_C)	Since birth rare Klippel–Trenaunay deformity /absence of valves
Primary (E_P)	Familial – undetermined cause wall theory or absence of valves
Secondary (E_S)	Post thrombotic Post traumatic Pregnancy Fibroid Ovarian cyst Abdominal lymphadenopathies Pelvic tumors Retroperitoneal Fibrosis Ascites Iliac vein thrombosis High flow and pressure states- AV fistula

In revised CEAP classification a new category (En) No venous etiology made out

The Anatomic classification **(A_S, A_D, or A_P)** is as detailed

Sites are described as superficial (A_S), deep (A_D), or perforating (A_P) .	
SUPERFICIAL VEINS (A_{S1-5})	
1	Telangiectasia or reticular veins
	Long saphenous vein
2	Above knee
3	Below knee
4	Short saphenous vein
5	Non saphenous
DEEP VEINS (AD $_{6-16}$)	
6	Inferior vena cava
	Iliac
7	Common
8	Internal
9	External
10	Pelvic: Gonadal, broad ligament
	Femoral
11	Common
12	Deep
13	Superficial

14	Popliteal
15	Tibial(anterior,posterior or peroneal)
16	Muscular (gastrocnemius, soleal, others)
PERFORATING VEINS (AP 17,18)	
17	Thigh
18	Calf

In revised CEAP classification a new category (An) no venous location identified

Pathophysiological Classification ($P_{R, O}$)

Reflux (P_R)
Obstruction (P_O)
Reflux and Obstruction ($P_{R,O}$)

In revised CEAP classification a new category (Pn) indicates NO reflux or obstruction could be determined

Diagnosis and evaluation:

Level 1: History and clinical examination hand held Doppler

CLINICAL FEATURES OF ULCER

1. Varicosities in front and back of the leg

When the patient present with varicosities in the leg, it is better to advise them on surgical management which avoids the complication of edema followed by lipodermatosclerosis and ulceration. If left untreated disease progresses

2. Ankle flare

3. Thickening, pigmentation, inflammation and induration of calf skin.

4. Ulcer on the medial aspect indicates long saphenous system incompetence usually present between calf muscles to just above the ankle

5.They develop in the lateral aspect if lesser saphenous incompetence is present.

6.Gently sloping edge.

If ulcer edge is elevated, biopsy is warranted to rule out malignant ulcer

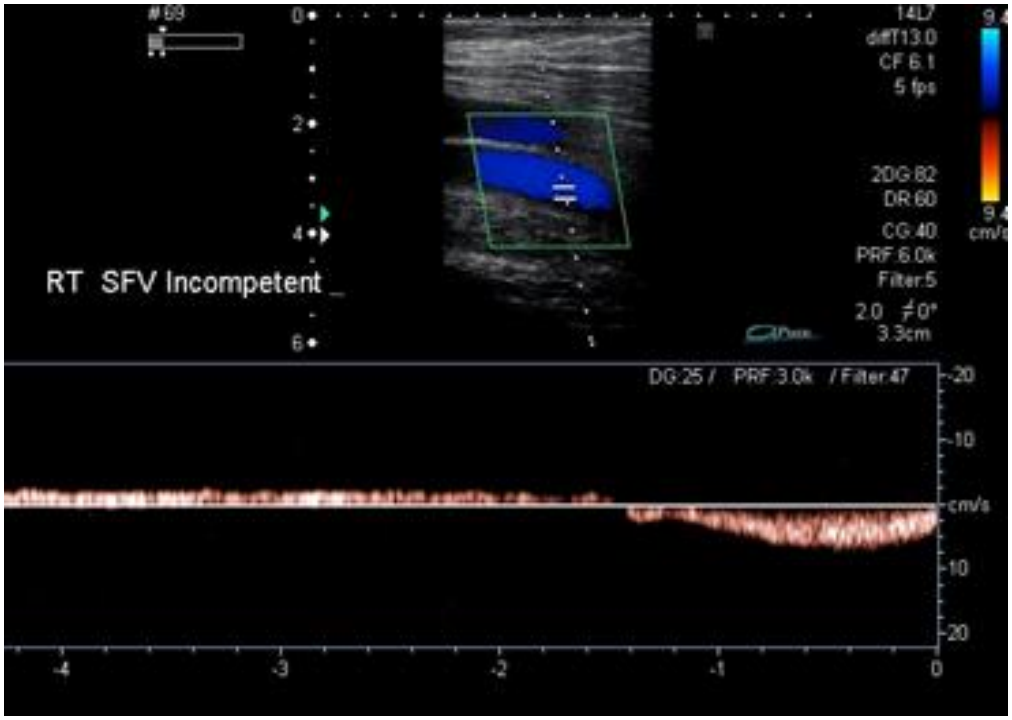
7.Base will have granulation, if secondarily infected slough will be present

DIFFERENTIAL DIAGNOSIS FOR LEG ULCERATION	
1	Venous disease: 65-73%
2	Arterial ischemic ulcers
3	Rheumatoid ulcers
4	Traumatic ulcers
5	neuropathic ulcers (diabetes)
6	neoplastic ulcers (squamous cell carcinoma and basal cell carcinoma)

Specific Investigation for ulcer

1	Full blood count
2	Erythrocyte sedimentation rate C reactive protein
3	Sickle cell test
4	Polycythemia
5	Blood and urine glucose
6	Ankle brachial pressure index
7	Antibody for rheumatoid arthritis
8	Bipedal ascending phlebography
9	Biopsy to R/O malignancies

Level 2: Duplex color scanning

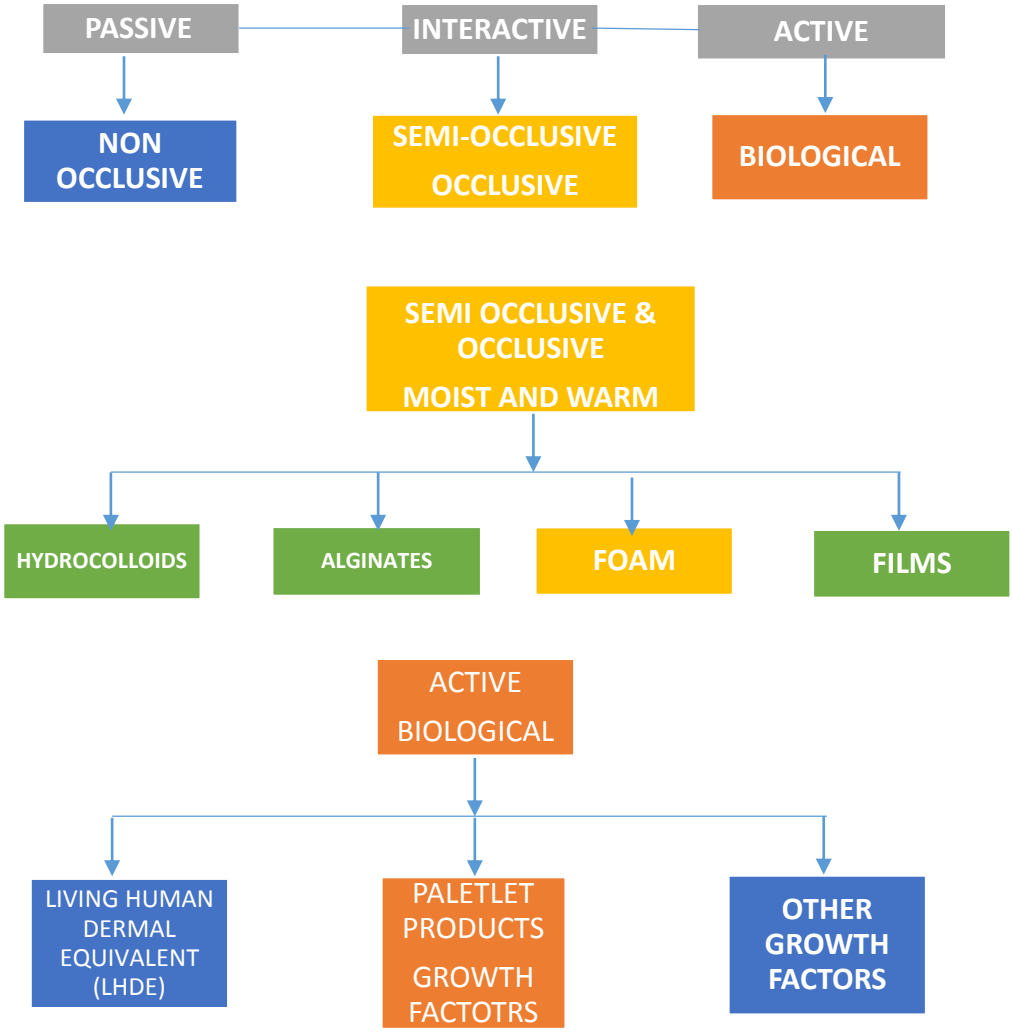


Level 3: Varicography, Ascending and descending venography, venous measurements, IVUS, spiral CT scan , MRV.

Descending venography showing incompetent femoral vein with competent profunda femoral

MANAGEMENT OF VENOUS ULCER

COMPRESSION BANDAGING REGIMENS



Charing Cross fur layer bandage- multilayered elastic compression

Steripaste three layer- Rigid multilayered system

Bland absorbent leak proof

MEDICAL MANAGEMENT- SUPPORTIVE

Alpha-benzopyrones	Coumarin
Gamma-benzopyrones (flavonoids)	Diosmin Micronized purified flavonoid 1000 1 or 2 Fraction Rutin and rutosides troxerutin (540)
Saponins	Escin/Aescin Ruscus extract
Other plant extracts	Anthocyanins Proanthocyanidines Ginkgo biloba
Synthetic products	Dobesilate Benzarone Naftazone
FIBRINOLYTIC THERAPY	Stanozolol tissue plasminogen activator oinments Dermatan sulfate Sulodexide, a highly purified glycosaminoglycan

Drugs that modify leukocyte metabolism	Pentoxifylline Prostaglandin E1 Prostacyclin analogs Iloprost Diosmin–hesperidin
PLATELET INHIBITORS	Aspirin Ifetroban
Antibiotics	For secondary bacterial infection

SCLEROTHERAPY

INDICATIONS

1	Superficial venules – spider veins <1 mm diameter
2	Varicosities 1-3 Mm Diameter, No Demonstrable Reflux
3	Post op residual veins
4	During follow up small recurrances
5	Congenital vascular malformation- Klippel– Trenaunay syndrome
6	Bleeding varicosities
7	Varies around ulcer bed promotes ulcer healing

Percutaneous laser therapy is also used for telangiectasia's

OPERATIVE PROCEDURES

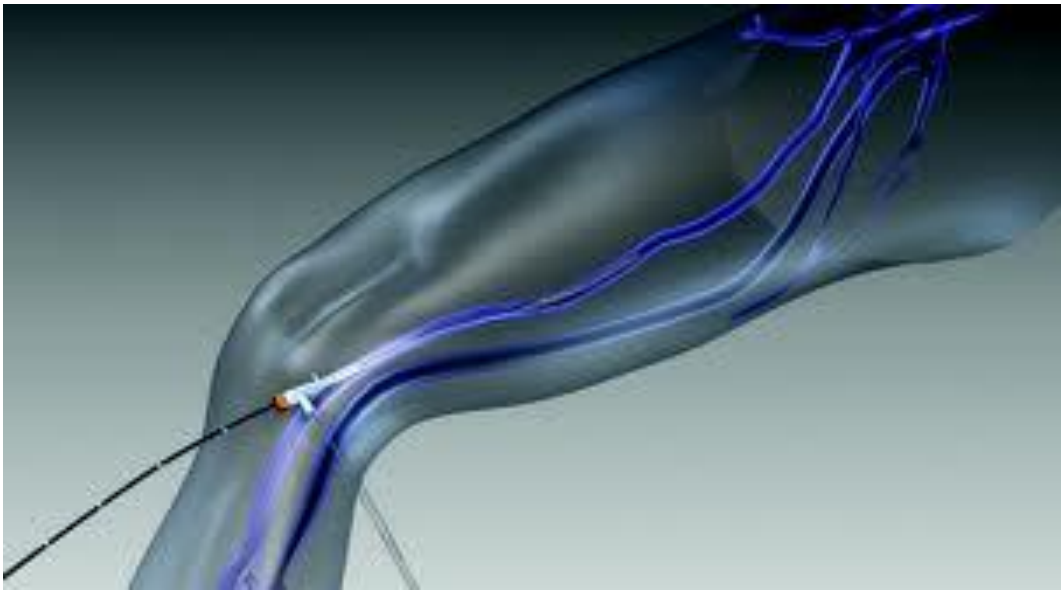
1	**Great Saphenous Vein**	**High ligation and inversion stripping of saphenous vein**
2	**Short saphenous vein**	**SPJ ligation**
3	**Deep venous system**	**Surgical repair, artificial valves reconstruction , grafting of thrombosed segment**
4	**Leg veins**	**Multiple stab avulsions and ambulatory phlebectomy**
5	**Perforators**	**Identify and ligate individual perforator**

BEFORE SURGERY

FOUR WEEKS POST SURGERY

RADIOFREQUENCY ABLATION

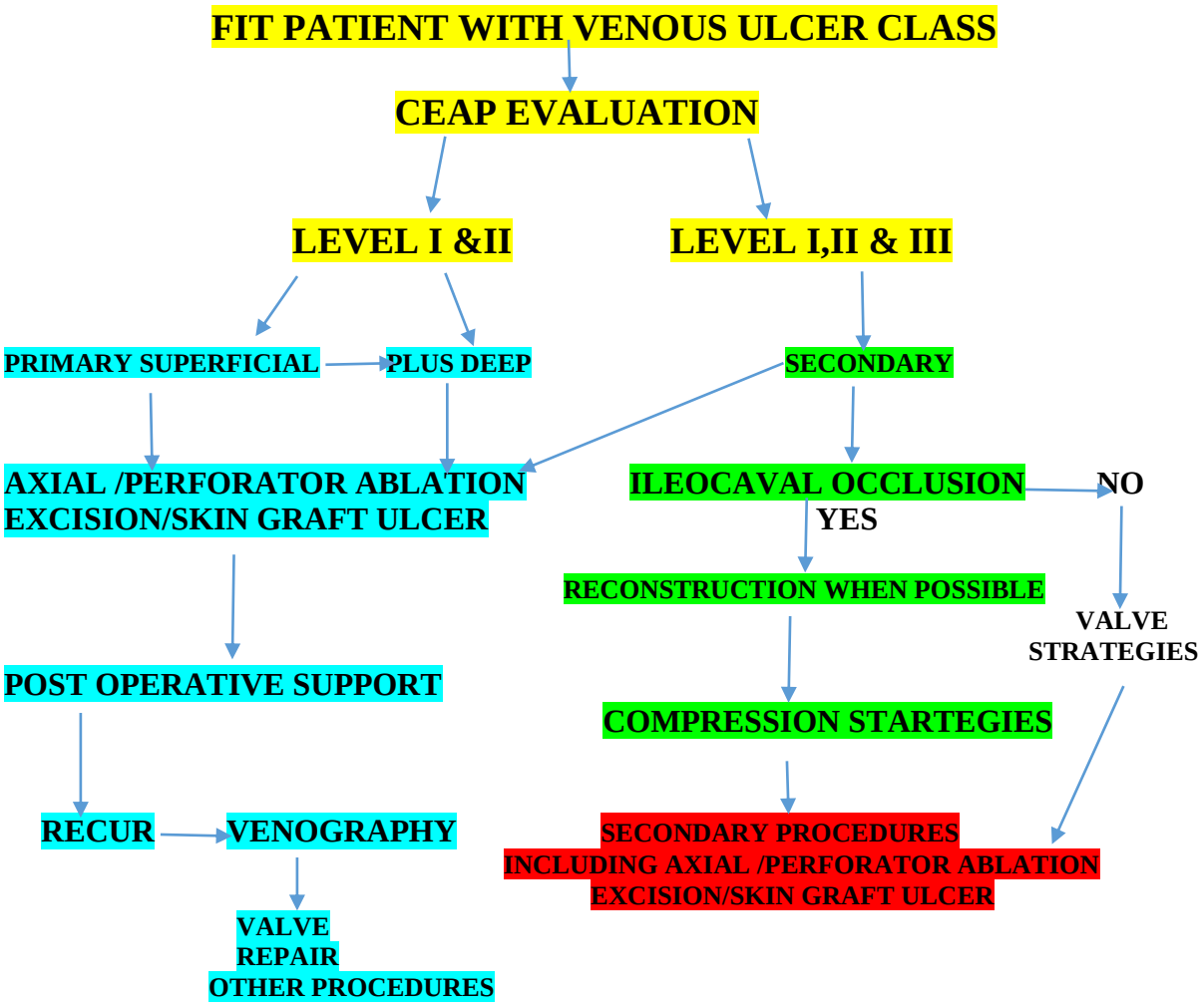
1	**Effective and safe treatment**
2	**Outcomes are comparable to stripping and ligation**
3	**There are less chances of morbidity, convalescence and complications so ideal primary option of management for high risk patients like those on anti-coagulants and obese individual**



ENDOVENOUS VENOUS LASER ABLATION TECHNIQUE

INDICATIONS	
1	**Superficial venous insufficiency**
2	**Reflux > 0.5 sec in duplex**
3	**Deep system patent**
4	**Vein conducive for cannulation**
5	**Adequate patient mobility**
ADVANTAGES	
1	**Removes target vein from venous circulation**
2	**Safe, tolerated well, complications are less frequently encountered**

ALGORITHM FOR VENOUS ULCER MANAGEMENT- CURRENT GUIDELINES



PREVENTION

1. Ulcer once healed should be periodically reevaluated in order to prevent recurrence.

2. Inspite of surgery patient needs to were compression stockings religiously

3. Proper hygiene

4. Appropriate occupation

5. Life style modification

RECENT ADVANCES

Vaccum assisted closure aids in faster healing	
Treating venous disorders in organized and evidenced based methodology	
Researches on	**Improved stenting**
	Biodegradable filters
	Better skin replacement
	Venous conduits
	Artificial valves
	Angiogenesis factors

MATERIALS AND METHODS

PATIENTS AND METHODS

Between December 2012 to November 2013 , the patients who had presented to the general surgery and vascular surgery outpatient department of Stanley Medical college hospital with features of venous ulcer or impending ulcer were admitted evaluated treated and periodically observed. The study was conducted in accordance with our institutional ethical committee guidelines

INCLUSION CRITERIA

1. Patients in the age group of 20 to 80 years
2. Both males and female
3. Patients with venous ulcer along with GSV varicosity (C4-6)
4. Patients with recurrent varicose ulcer.

EXCLUSION CRITERIA

1. Patients in CEAP 1-3
2. Patients with Diabetes
3. Patients with Peripheral arterial occlusive disease
4. Patients with Vasculitis
5. Patients with Malignant ulcer
6. Patients with Phlebothrombosis or post-thrombotic syndrome
7. Patients with congenital venous anomalies *Klippel-Trenaunay*
8. Patients with lymphedema & lipedema,
9. Women during pregnancy or postpartum period
10. Patients with heart failure, renal insufficiency, severe concomitant disease, connective tissue disorders

METHODOLOGY

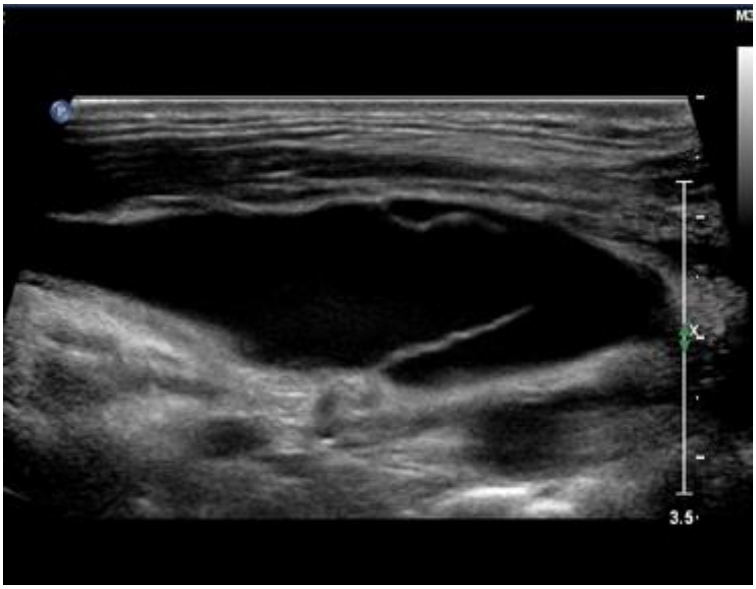
The patients who reported to the outpatient department were carefully examined and based on the inclusion and exclusion criteria they were taken into the study patients were included based on inclusion and exclusion criteria

They were informed about the study and a written consent was obtained

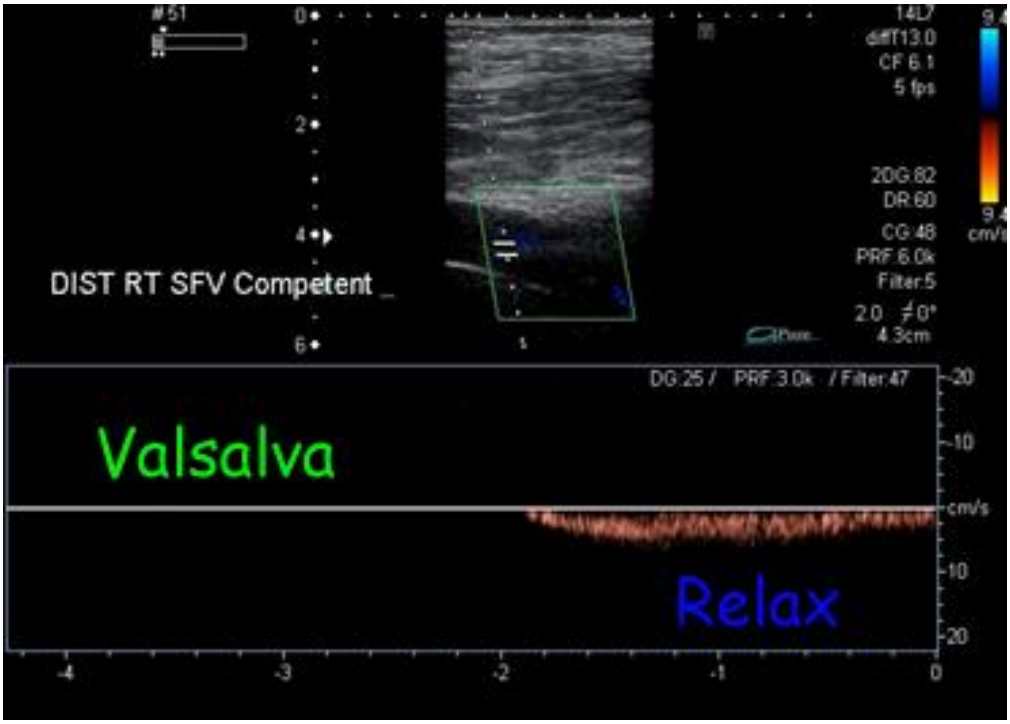
After documentation of clinical history, examination finding and basic investigations

Patients were subjected to Duplex Scan - The superficial and deep veins would be examined for patency and competence, site of reflux.

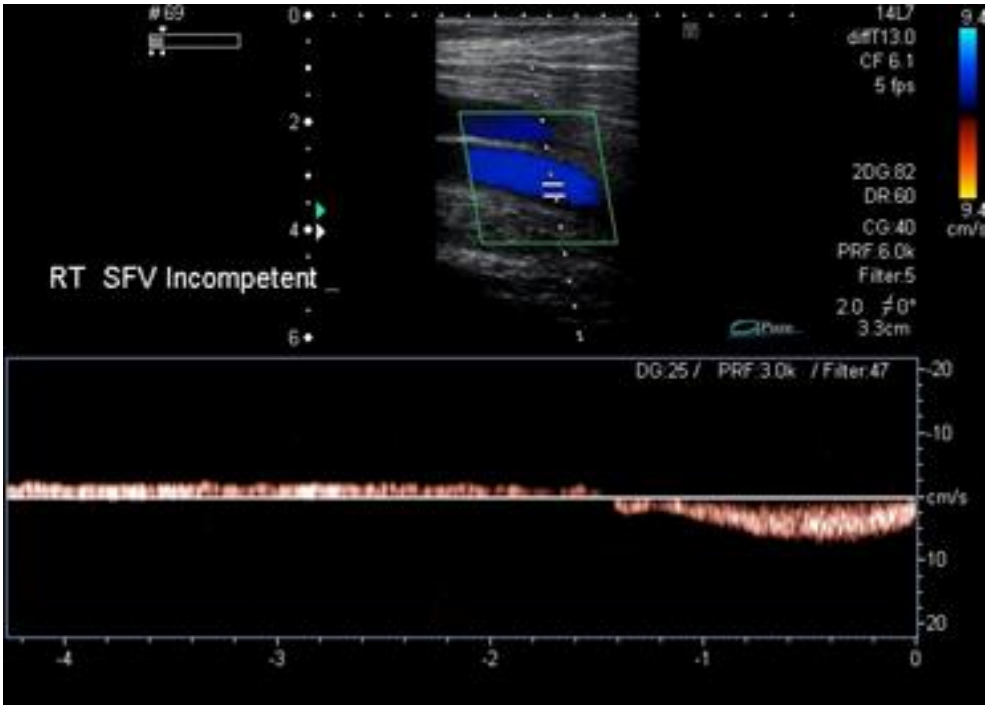
Normal Valve



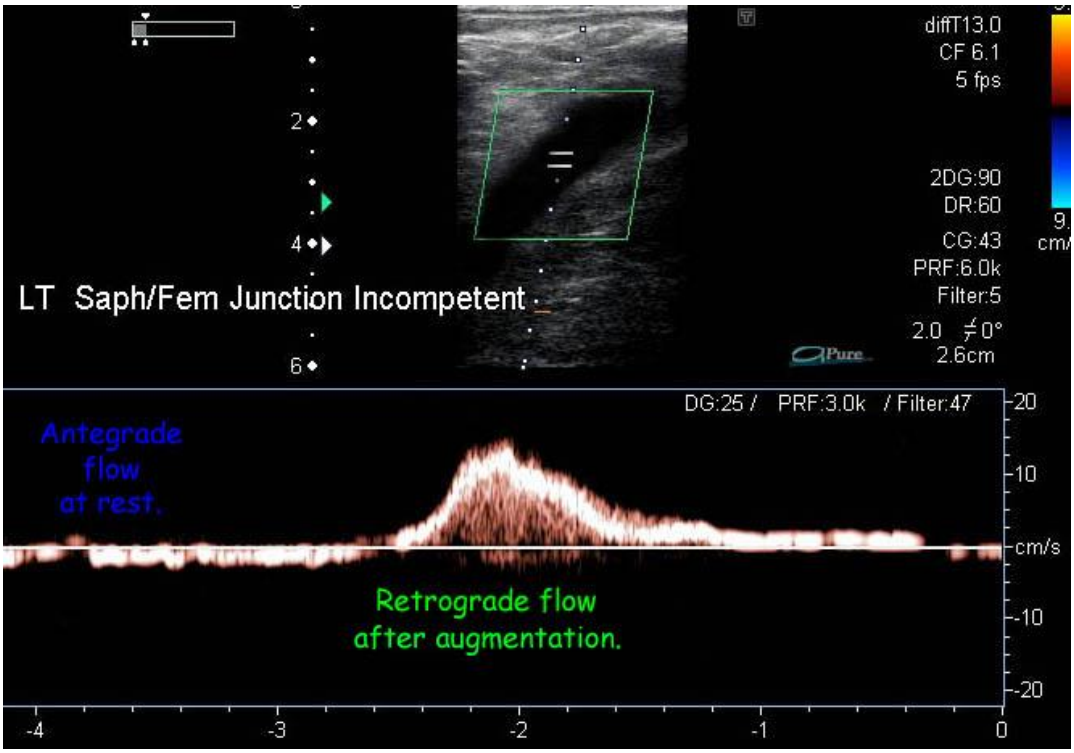
Here we can see the distal Saphenofemoral vein is competent even on Valsalva effect



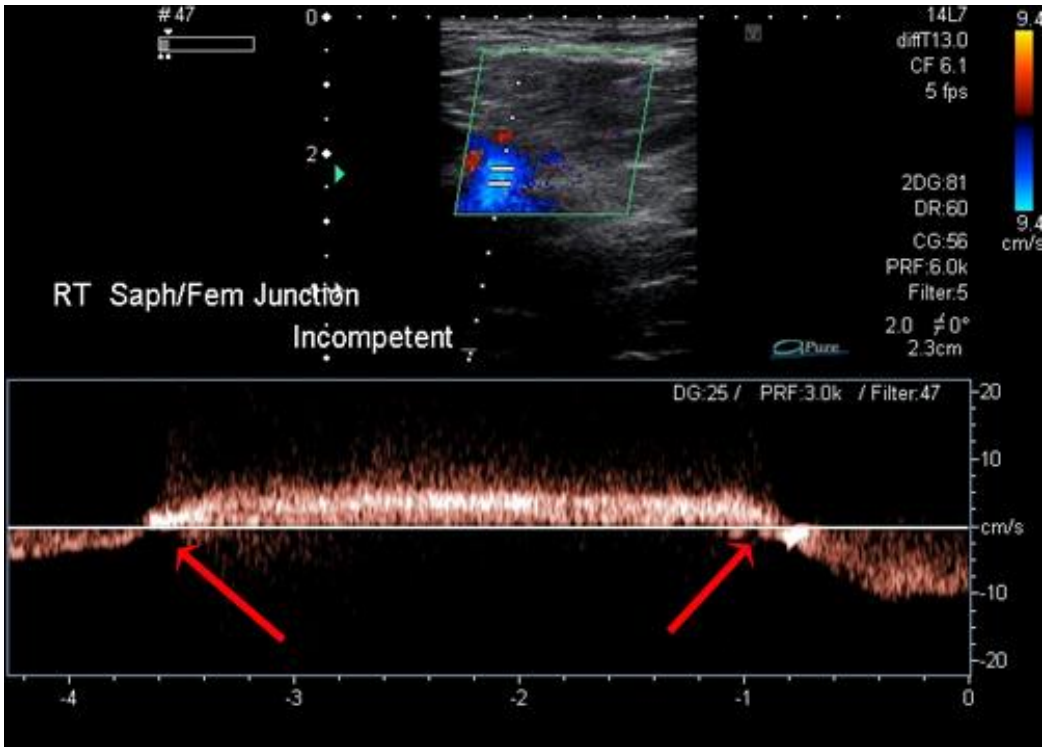
Whereas the below picture shows the incompetence of the valve and reverse flow



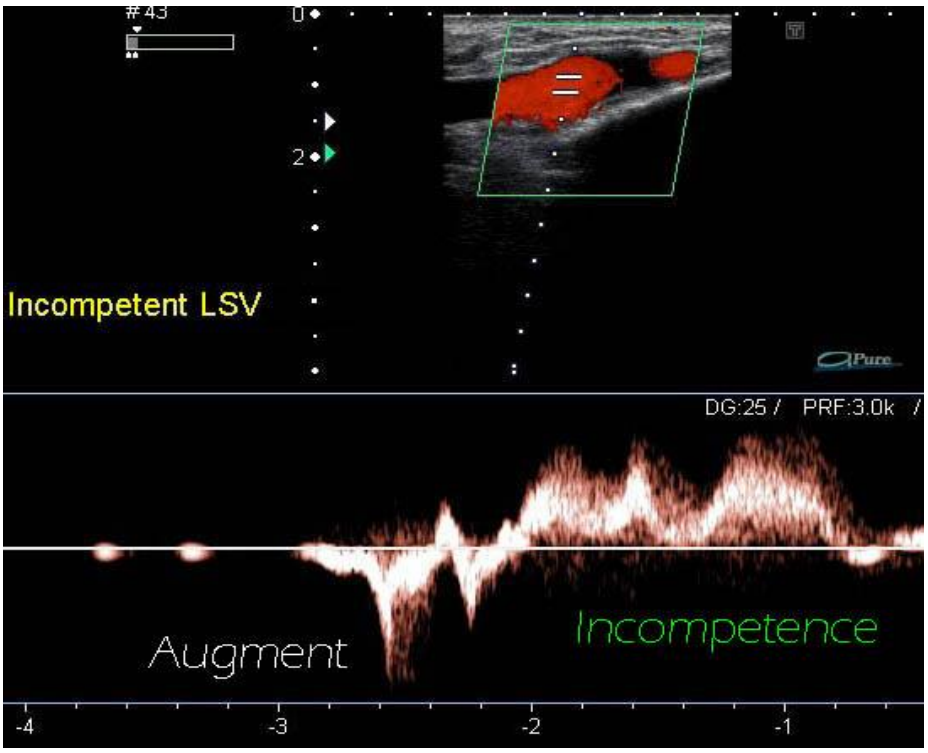
The saphenofemoral junction which is incompetent on augmentation show the reflux

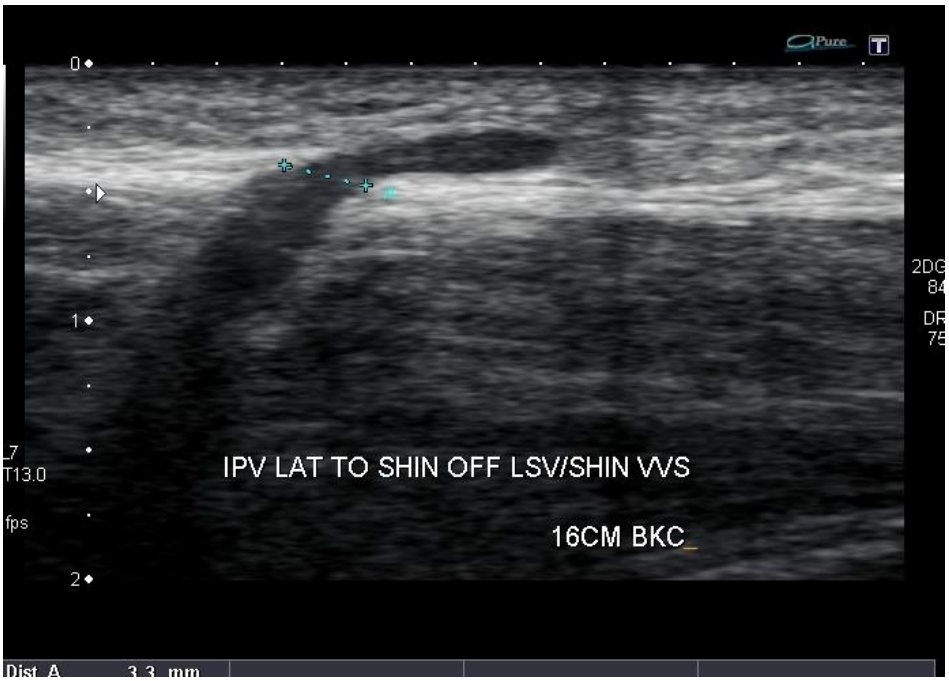


Sapheno femoral junction incompetence following Valsalva maneuver



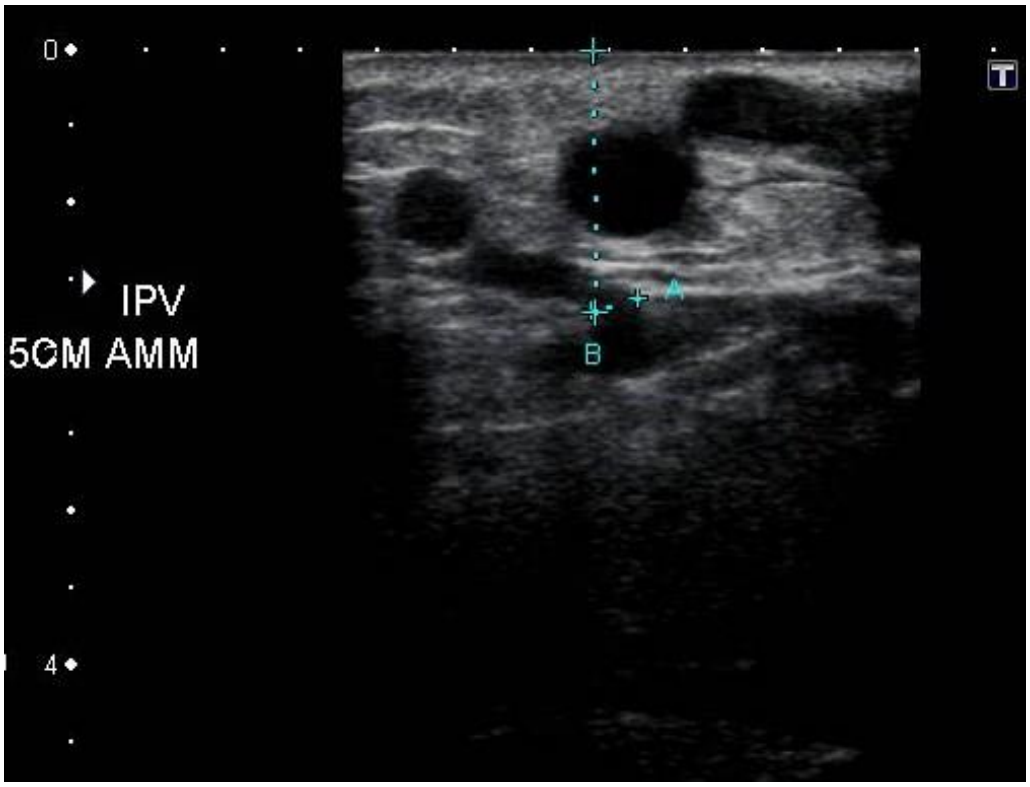
This duplex depict the incompetence of leg veins in ulcer patients on augmentation





It clearly shows how well the problematic area can be documented before the procedure

This duplex shows an incompetent varix

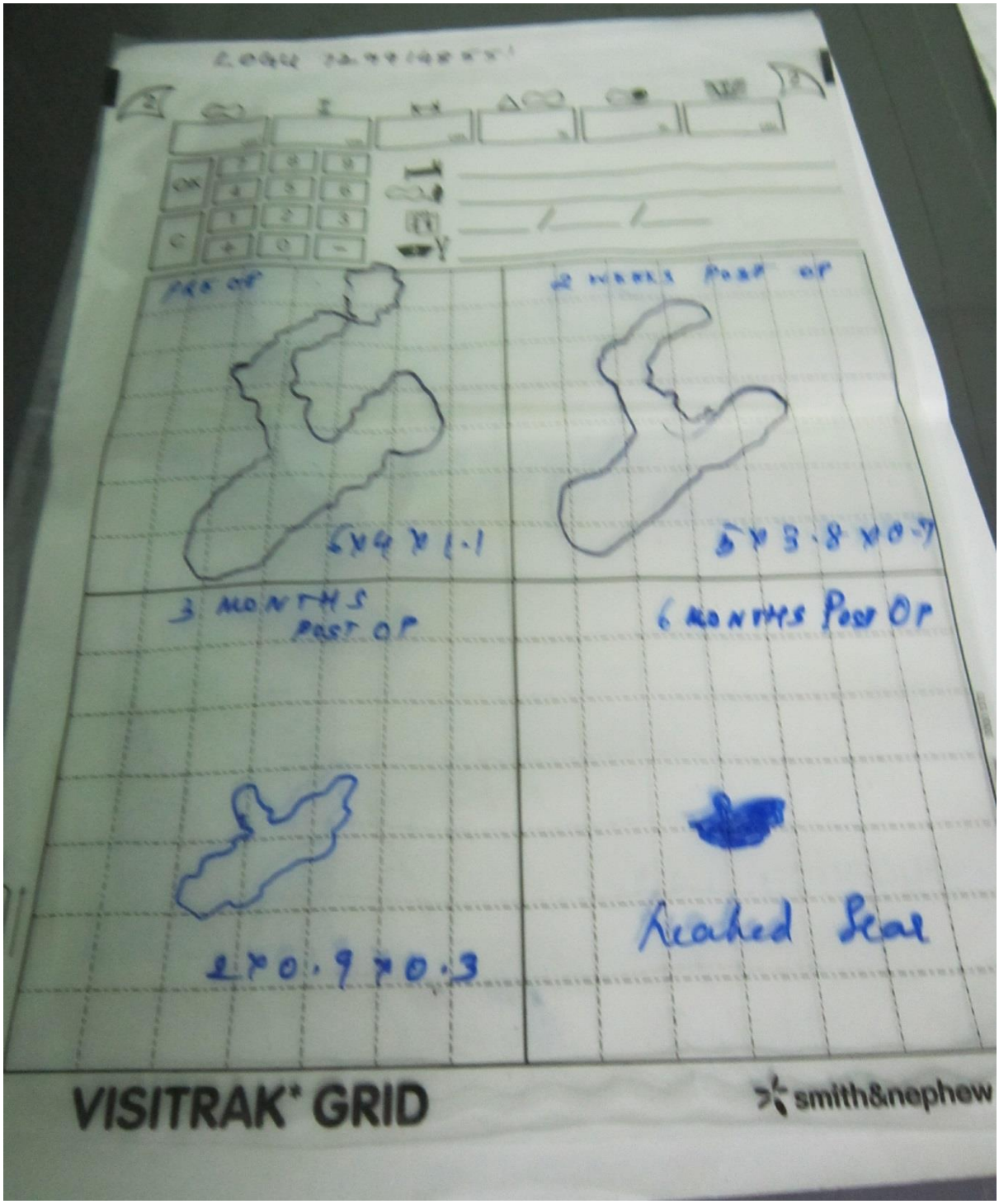


Pretreatment evaluation helps in targeting the exact pathophysiology for quicker healing.

Once the patient has been clinically and radiologically evaluated , before instituting the treatment he size and depth of the ulcer are computed using a visitrak

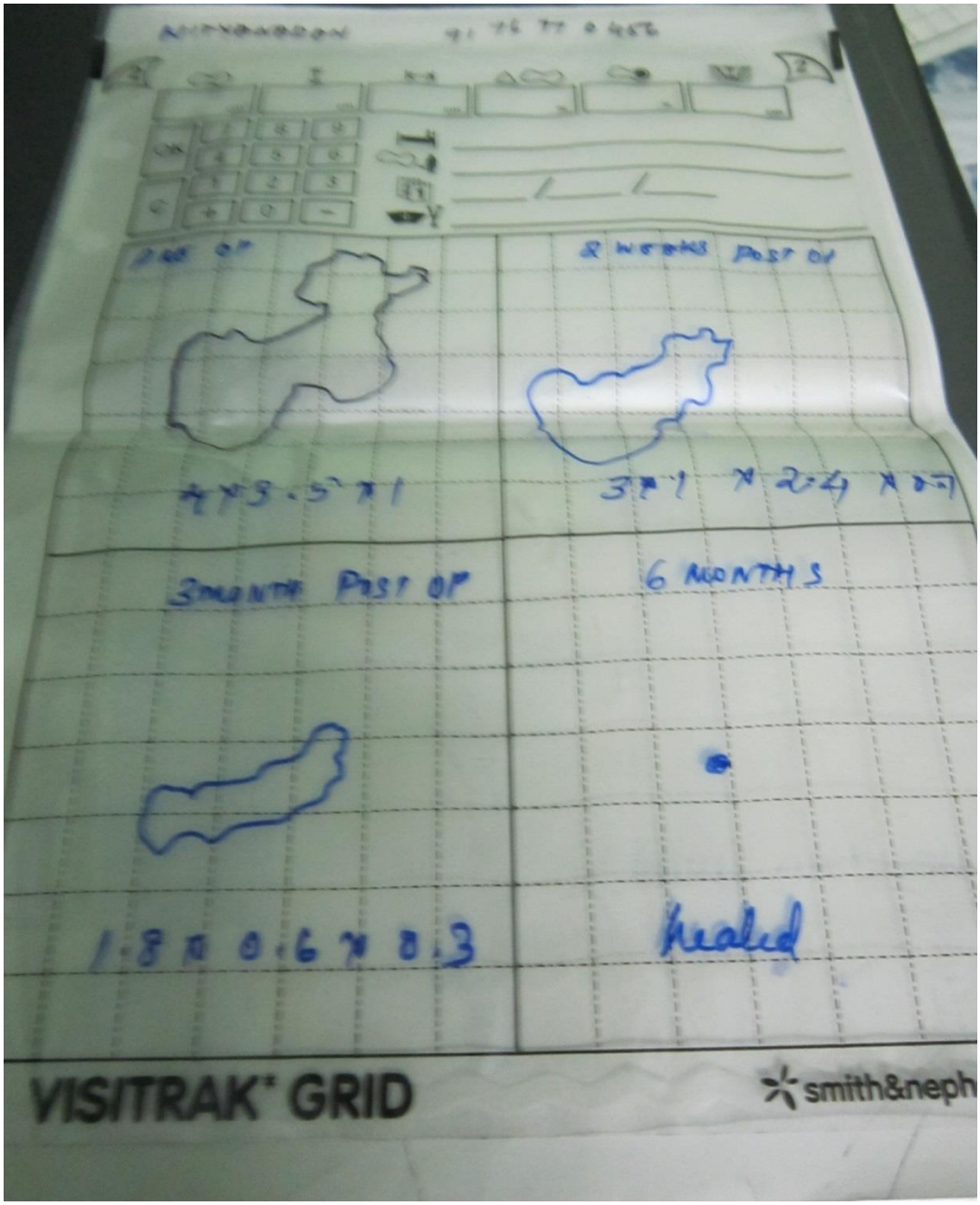
So that proper follow up and exact time required for follow up can be documented

Few Visitrak s showing how the ulcer slowly regresses in size



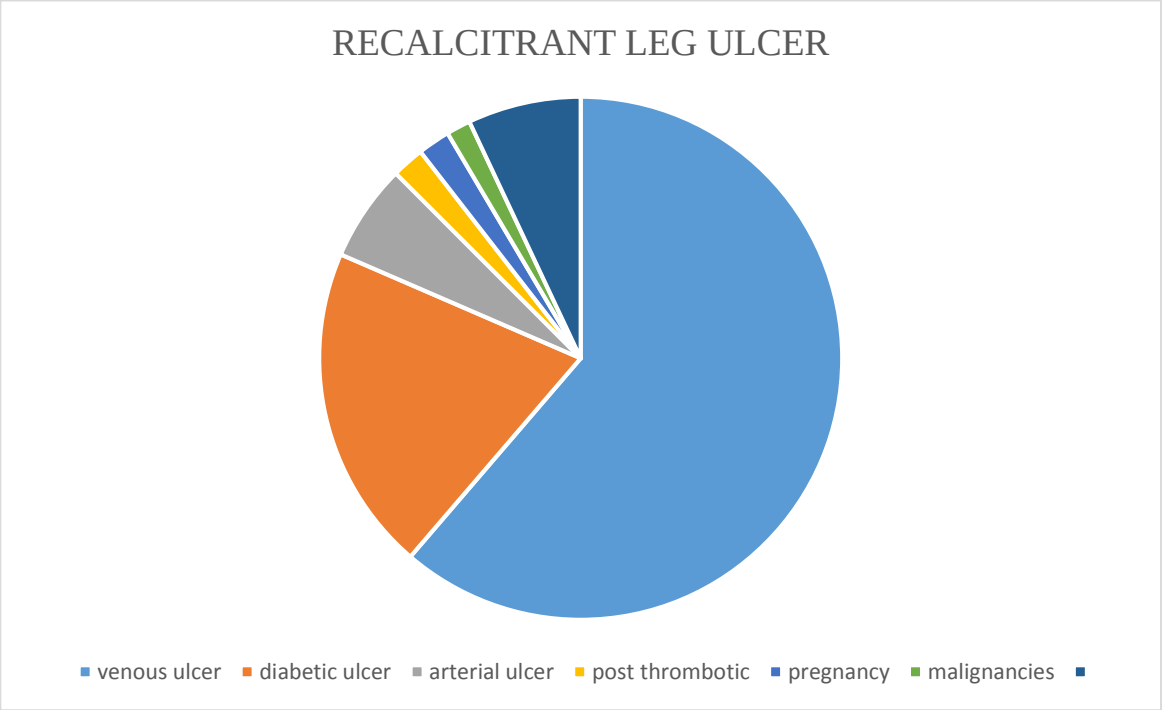
Follow-up intervals were within 1 week, monthly until ulcer healing, and 6 months thereafter

In Most of the patients the ulcer regressed completely and there were a few patients were even the discoloration of skin was changing when the limb was taken care off.



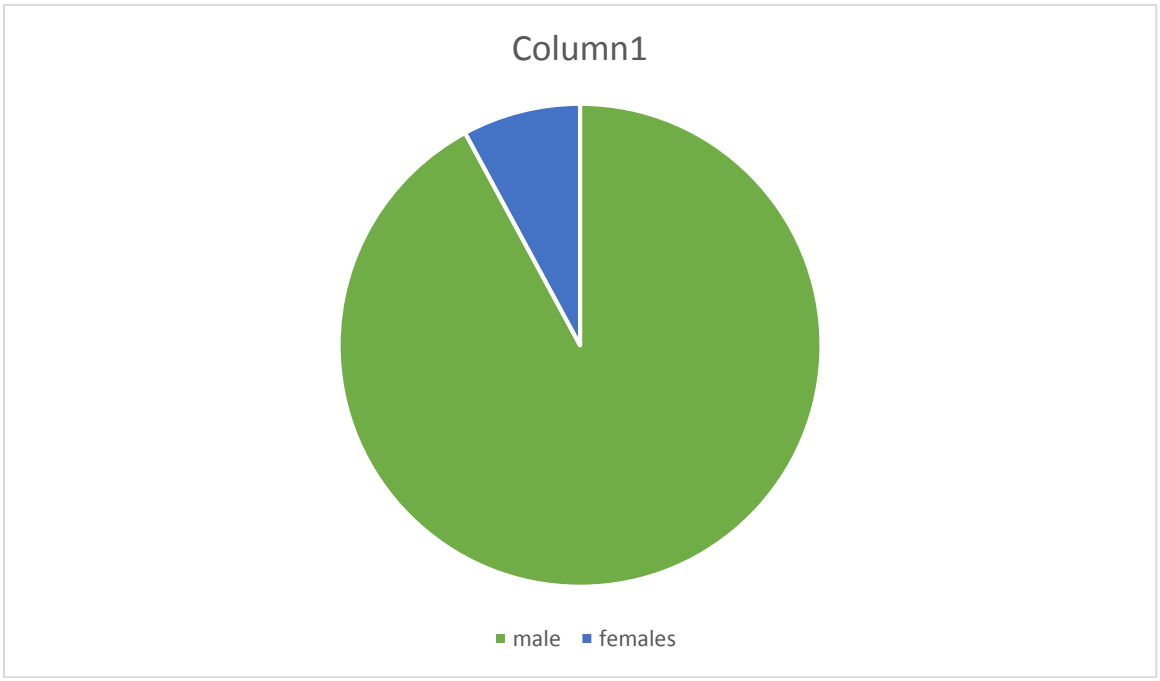
RESULTS, OBSERVATIONS AND CHARTS

During the study period from December 2012 and November 2013 around 124 patients present to the General surgery and vascular surgery OPD of Stanley medical college. They were carefully evaluated and based on the inclusion and exclusion criteria only 76 patients fit into the study

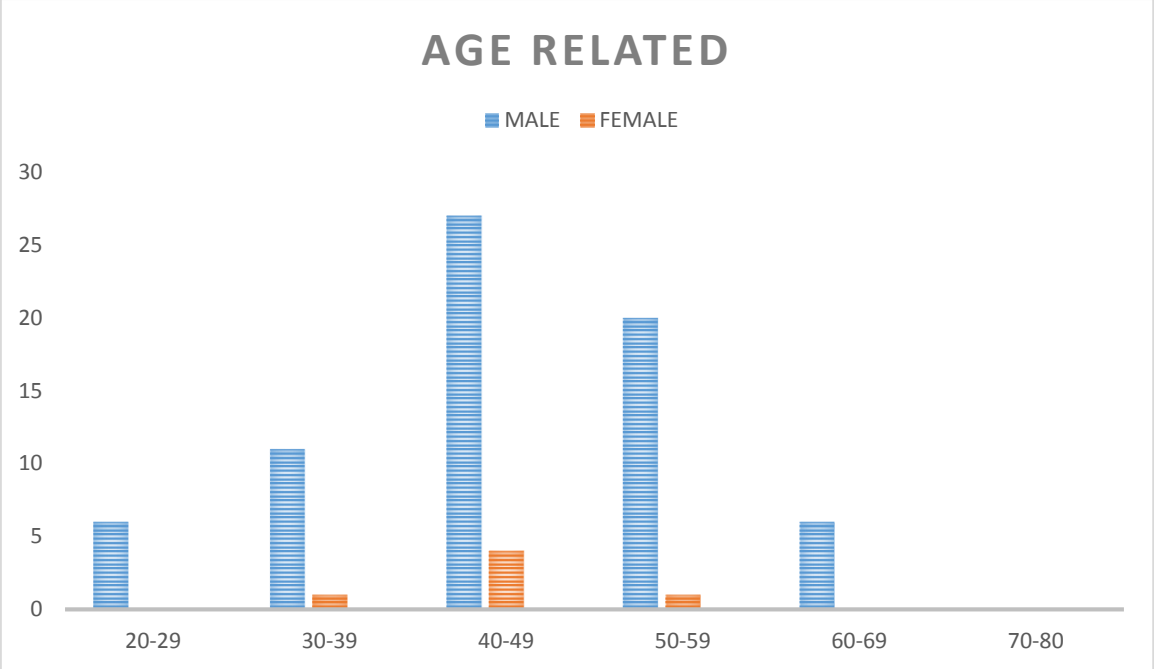


Which clearly states that 61 .29% of patients with chronic non healing ulcers in the leg were purely venous during their productive age. 38.71% had ulcers due to other reasons or added comorbid conditions

Of the 76 patients, 70 males 6 females

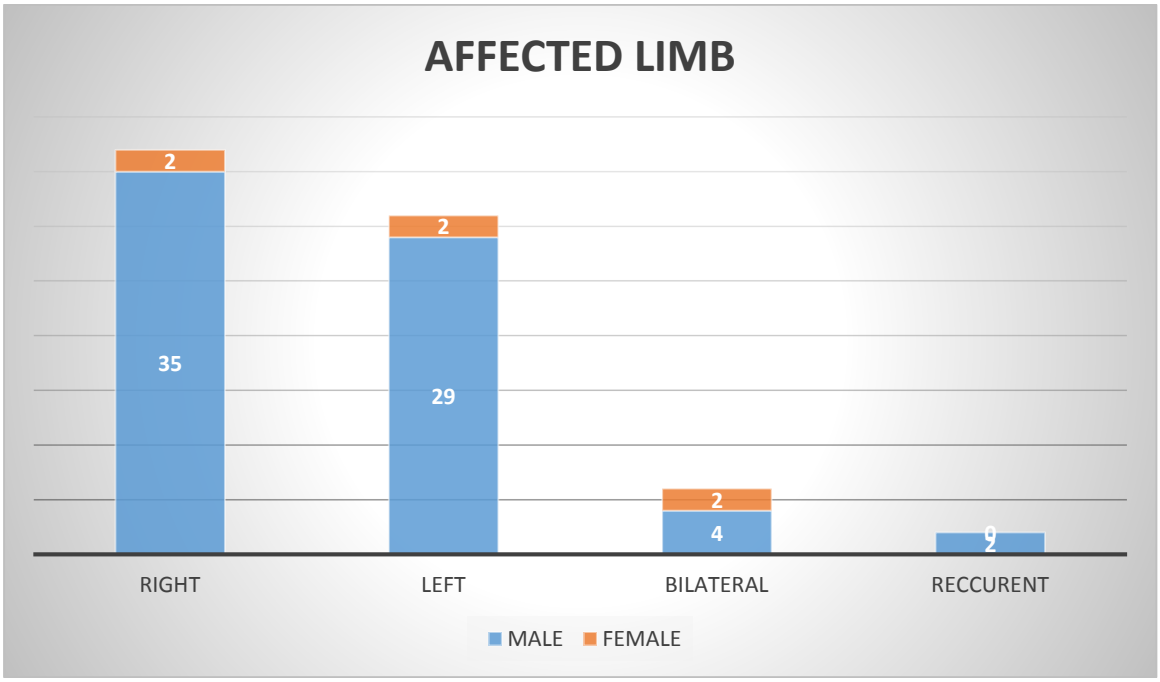


We see that most of the patients who have presented are men 92% , may be for two reasons they are the people who are the employed outside , culture of Indian women is to be more of a home maker even if they are employed .



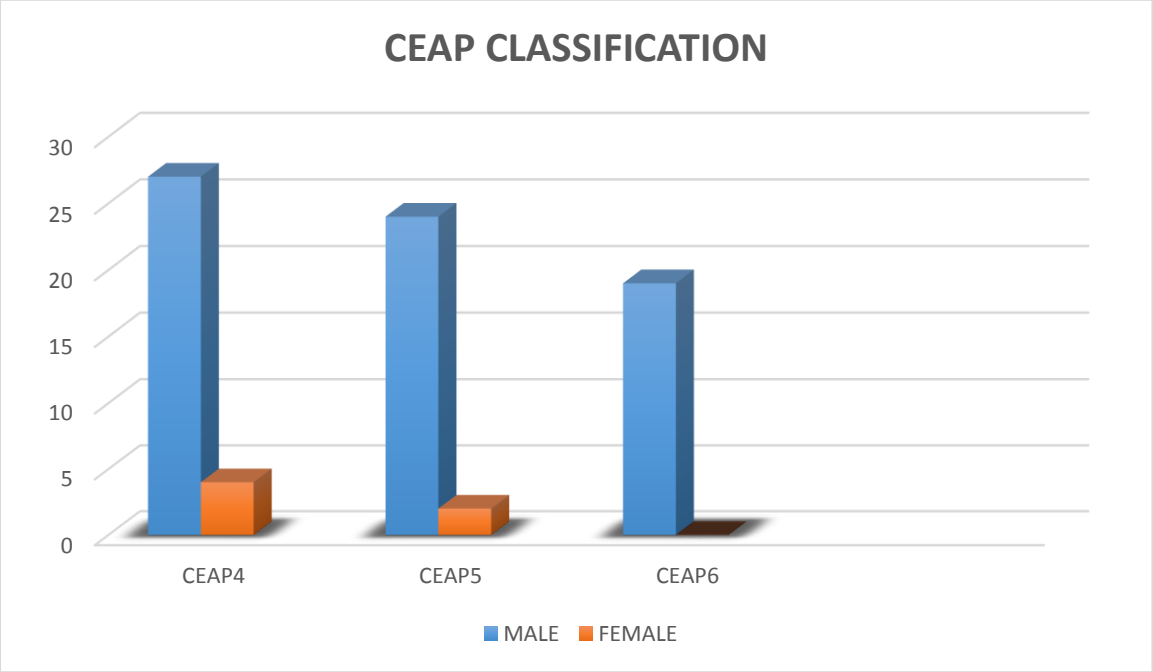
Among the patients who presented to the OPD it was noticed that majority of them 42% were between the age of 40- 49 in both men and women , followed 27.6 % by the 50-59 age group, then 15% in 30-39 , 7% among 60-69 and 20-29 age groups.

LIMB MOST COMMONLY AFFECTED



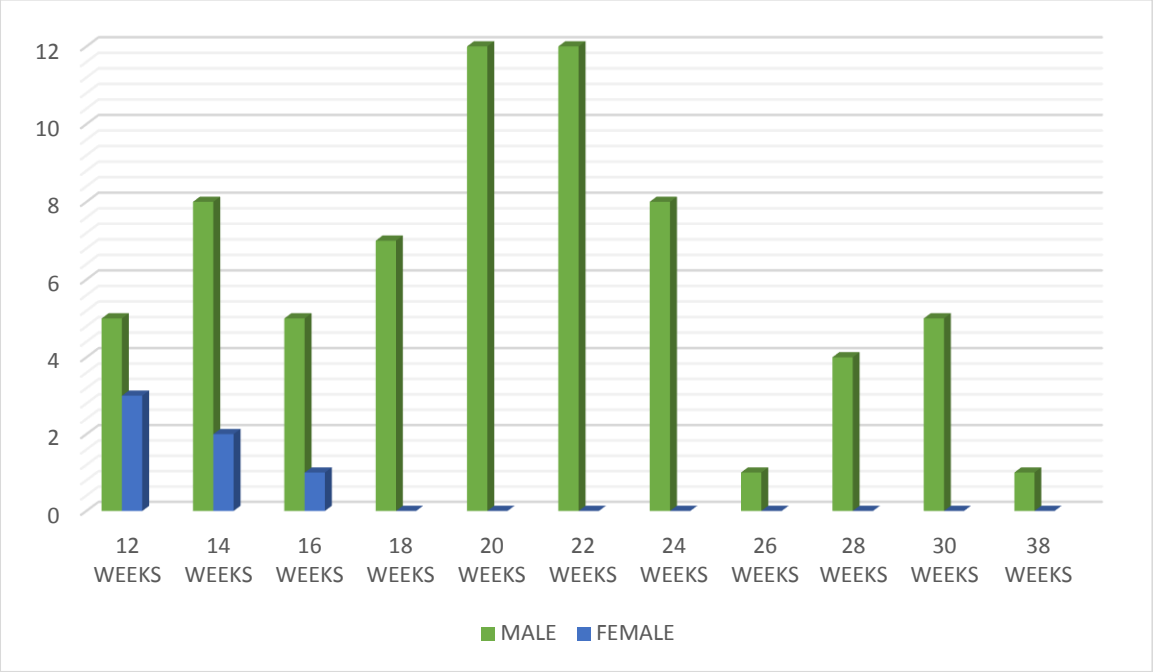
Among men the right lower limb 48 % was a little over the left 40.7 % followed by bilateral 7 % and recurrent. Whereas in women both right, left and bilateral were equally present. May be the occupation and the dependency of using the limb matters

CEAP classification



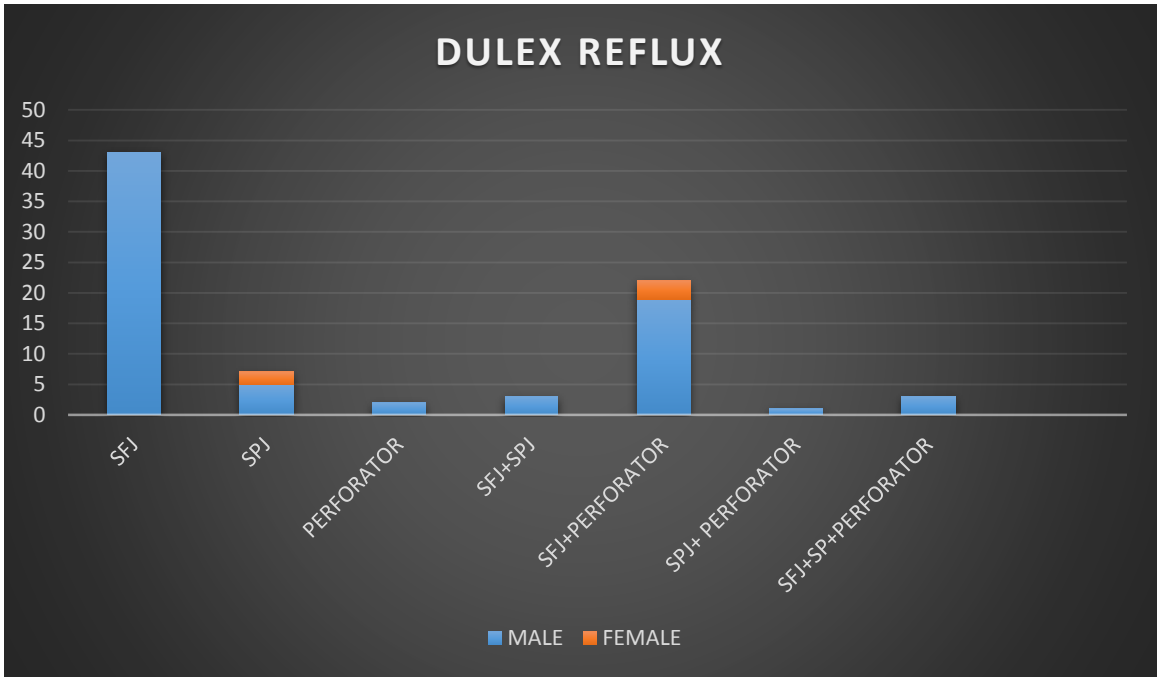
More no of patients in both male and female were grouped under CEAP 4 followed by CEAP 5 and then CEAP 6

DURATION OF ULCER PRE TREATMENT



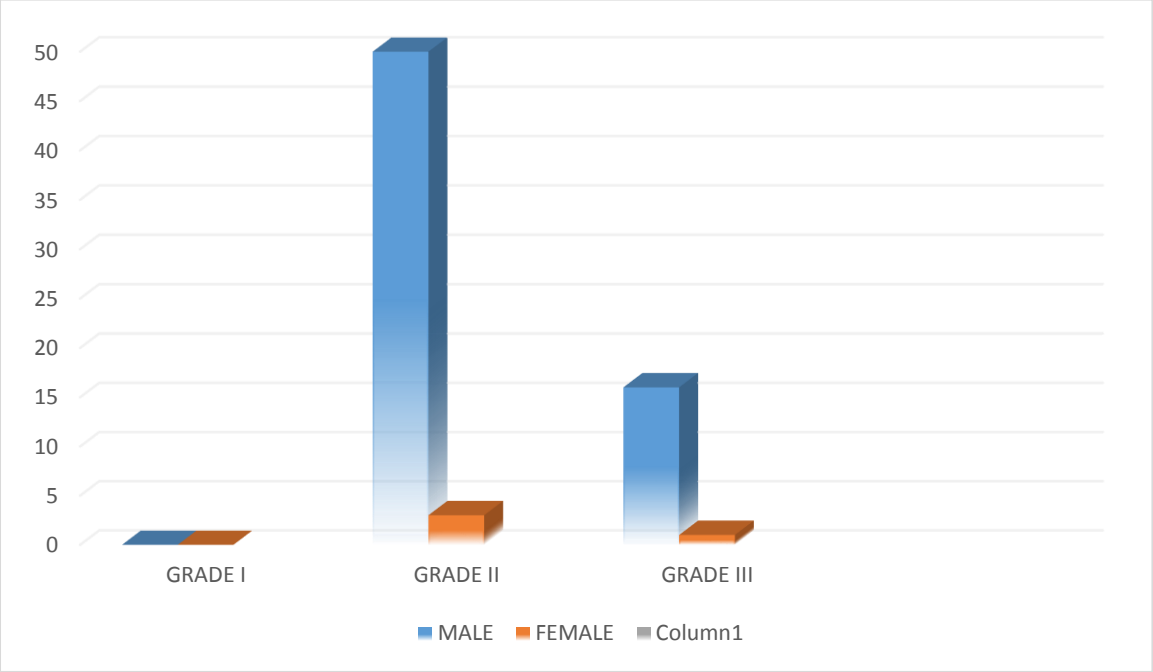
The patients had the ulcer between 12 weeks to a maximum of 38 weeks duration with or without treatment but majority of them had ulcer for a duration of about 20-22 weeks. Most of the patients had tried conservative means of management or some other alternative form of medicine all in vain and they seek medical help only when they feel it was turning a disability and affecting their occupation

DUPLEX REFLUX



These patients were subjected to color duplex which showed most of patients had reflux in Sapheno-femoral junction 56.5 % (43) followed by SFJ + perforator reflux 28.9 % (19/3) and then SPJ reflux 7% (5/2) . Combination of SFJ+ SPJ+Perforator reflux were present only among 4 % (3 patients).

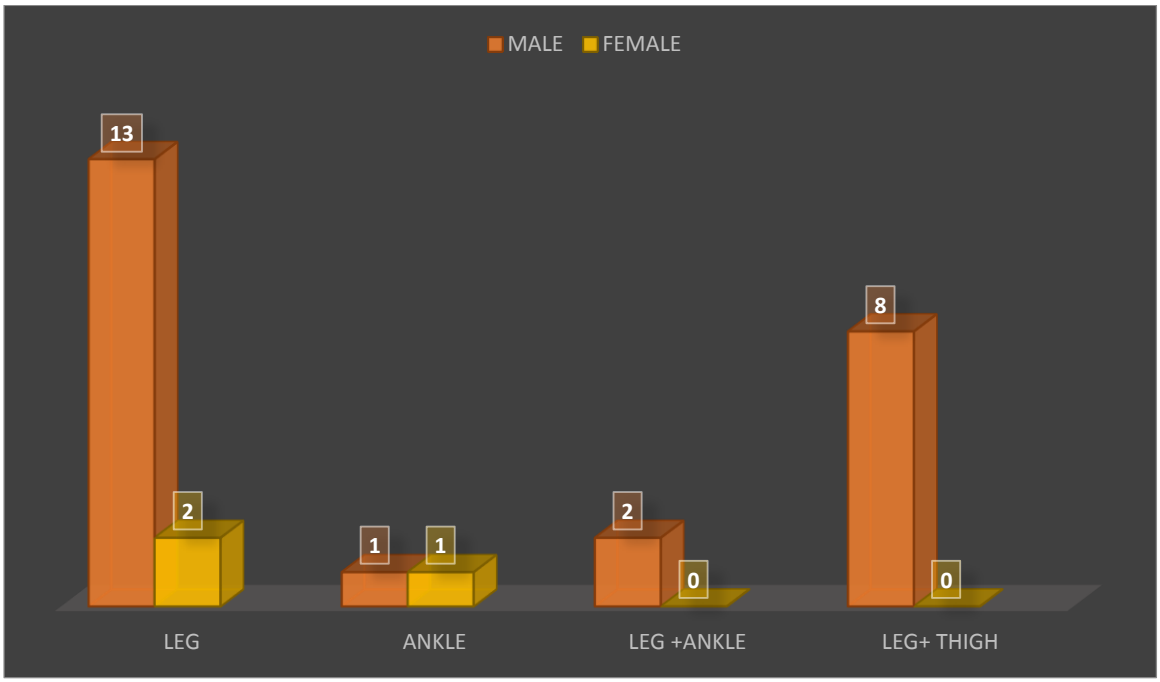
SFJ REFLUX GRADE



Among SFJ reflux grade II 69.7 % (50/3) dominated over grade III 22.3 % (16/1)

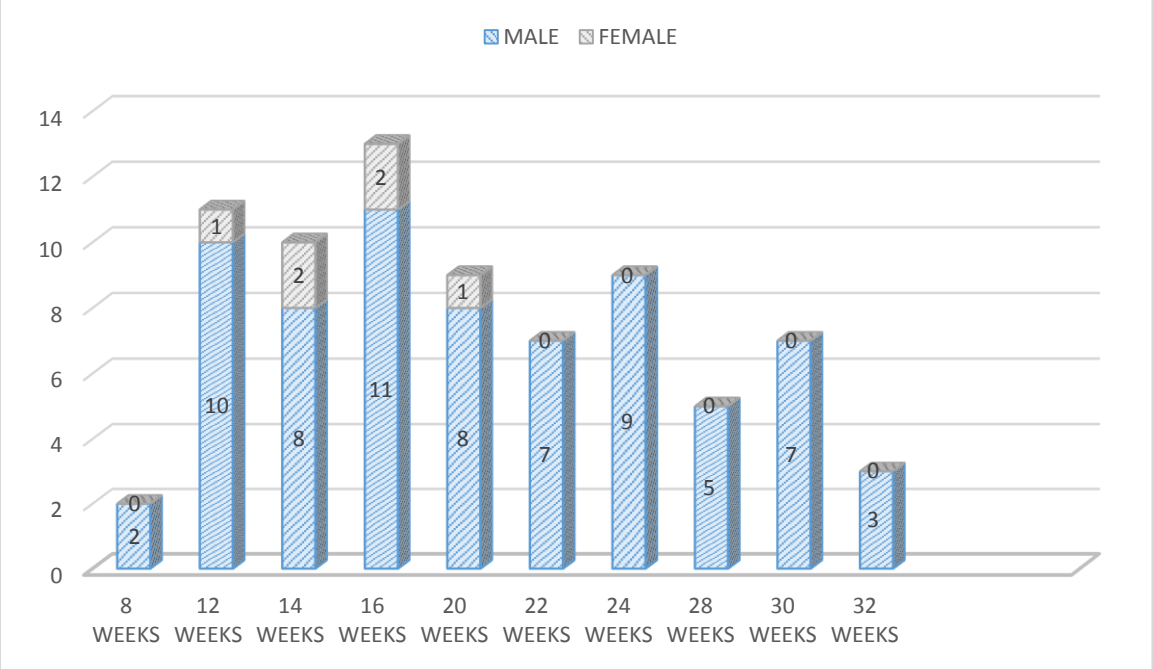
The cut off value for large veins like common femoral, femoral and popliteal was > 1000ms.For superficial veins, deep femoral, deep calf axial and muscular veins the value was 500ms, in perforating veins it was 350ms.A reflux for >0.5 sec is taken as abnormal, they were accordingly graded into three grades.

PERFORATOR SITE



Reflux site among perforators were again individually documented for the thigh, leg and ankle perforators It was seen that in the study most of the patients perforators of the leg were at fault in fifteen of them (13/2), the leg along with thigh had reflux in 10 patients (8/2), leg and ankle perforators had reflux in 2 patients (2/0), only Ankle in (1/1).

SEX RELATED HEALING TIME



Most of the wound healed by 16 weeks following treatment in both sexes (11/2),12 weeks (10/1), 24 weeks(9/0), 14 weeks (8/2).

Minimum healing time was 8 weeks among two men and it took nearly as long as 32 weeks to heal among 3 other men

ANALYSIS ON THE AGE GROUP AND SFJ REFLUX ON THEM

Age in years

	N	Mean	Std. Deviation	Min	Max	significance
No reflux	4	36.00	14.095	21	49	.088
Grade II	18	42.72	14.150	20	68	
Grade III	54	46.39	8.201	30	65	
Total	76	44.97	10.383	20	68	

Multiple Comparisons

Duplex Scan	Duplex Scan	Mean Difference	Significance
No Reflux	Grade II	-6.72	.079
	Grade III	-10.39	
Grade II	Normal	6.72	
	Grade III	-3.67	
Grade III	Normal	10.39	
	Grade II	3.67	

It was seen that the age was not that significant between groups and in general population who had reflux disease mostly all age group patients 20-68 in grade II and 30-65 years of age among grade III were observed

AN ANALYSIS ON THE AGE GROUP OF PEOPLE AND THE SPJ REFLUX

	SPJ Reflux	N	Mean	Std. Deviation	Sig. (2-tailed)
Age in years	Positive	11	46.91	8.893	.507
	Negative	65	44.65	10.641	.460

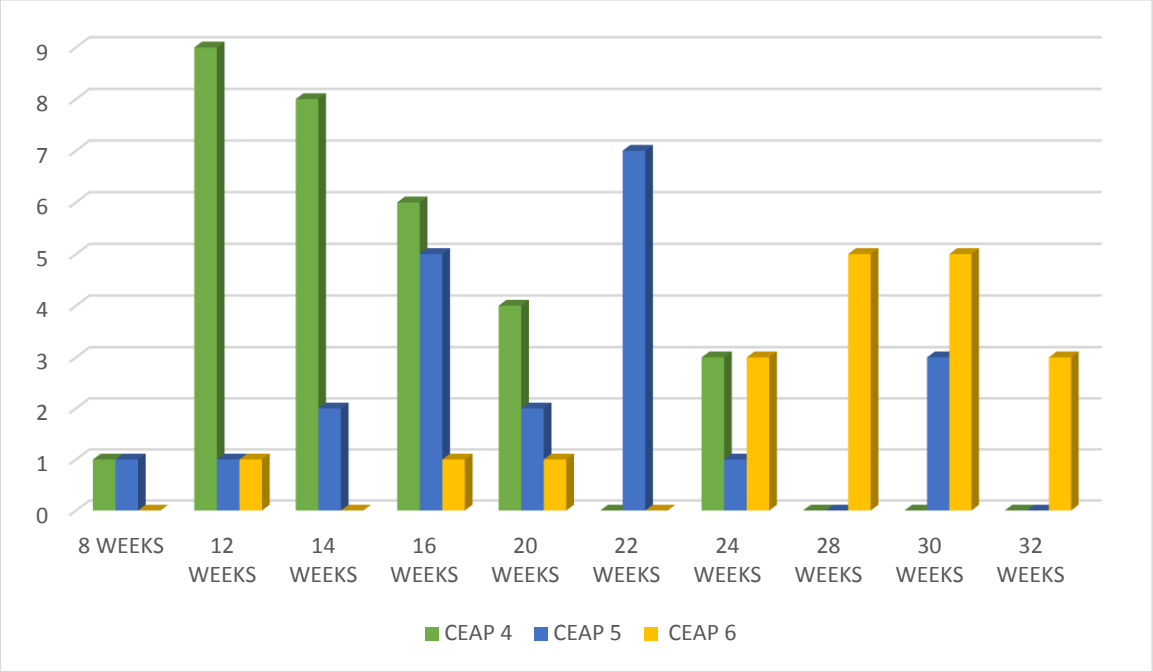
The analysis showed that it was not statistically significant

ANALYSIS ON THE AGE GROUP AND THE PERFORATOR REFLUX IN THEM

Perforator	N	Mean	Std. Deviation	Sig. (2-tailed)
Age in years Positive	27	46.26	11.186	0.427
Negative	49	44.27	9.962	0.443

Neither did this make an impact on the patient who had this reflux and their age.

CEAP RELATED HEALING TIME



Most of the patients in CEAP 4 the ulcer healed by 12 weeks (9), the range was between 8 weeks to a maximum of 24 weeks

Among CEAP 5 group majority of ulcer healed by 22 weeks, the range was between 8 weeks to a maximum of 30 weeks

Among CEAP 6 group majority of ulcer healed by 28-30 weeks, the range was between 12 weeks to a maximum of 32 weeks

CEAP AND ULCER HEALING TIME

Ulcer Healing in weeks

CEAP	N	Mean	Std. Deviation	Significance
4	31	15.35	4.013	**<.001**
5	26	20.08	5.642	
6	19	26.63	5.500	
Total	76	19.79	6.658	

This study clearly proves that there is significant association between the class of CEAP into which the patients are grouped and their duration of ulcer healing.

It is statistically very significant among patients belonging to this group CEAP4/5/6 as when those who don’t belong to them

Multiple Comparisons

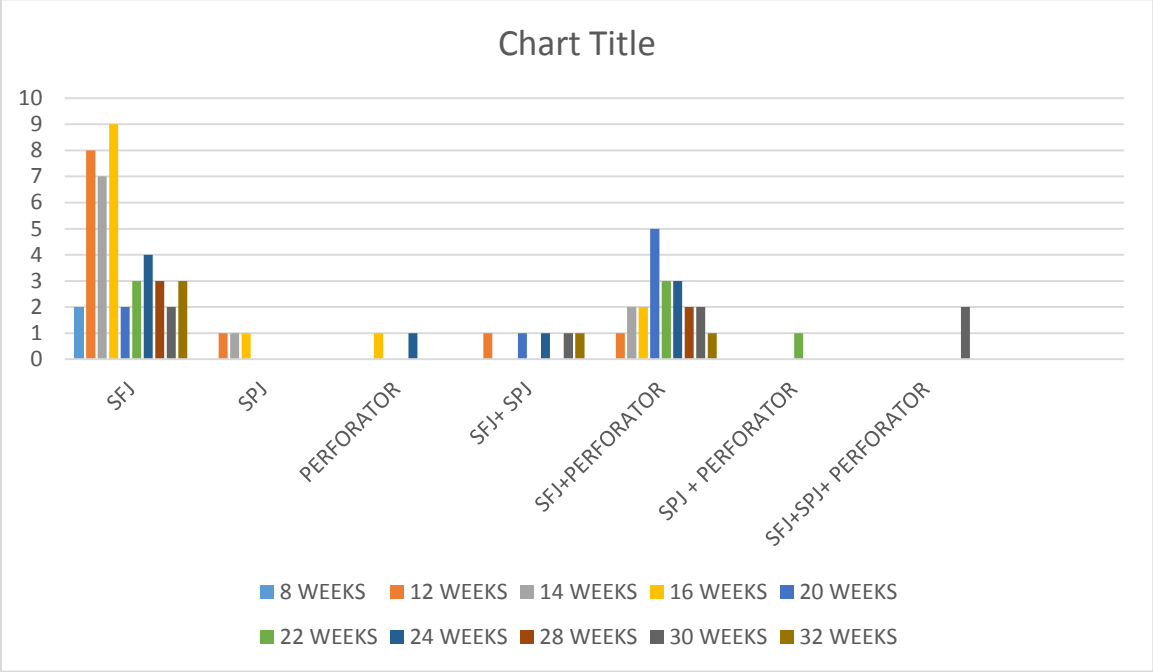
Dependent Variable: Age in years

CEAP	CEAP	Mean Difference	Significance
4	5	-8.43(*)	1.000
	6	-11.46(*)	
5	4	8.43(*)	
	6	-3.03	
6	4	11.46(*)	
	5	3.03	0.492

* The mean difference is significant at the .05 level.

Multiple comparison between groups also prove that they are significant and those who belong to CEAP 6 take a longer time then those who belong to CEAP 5 or CEAP 4.

REFLUX SITE RELATED HEALING TIME



Among patients with SFJ the healing time ranged between 8-32 weeks with majority taking 16 weeks' time

SPJ the healing time ranged between 12-16 weeks

Perforator the healing time ranged between 16-24 weeks

SFJ+ SPJ the healing time ranged between 12-32 weeks with

SFJ + PERFORATOR the healing time ranged between 12-32 weeks with majority taking 20 weeks' time

SPJ+ PERFORATOR the healing time 22 weeks

SFJ+ SPJ + PERFORATOR healing time is 30 weeks

SFJ reflux Descriptive

Ulcer Healing in weeks

	N	Mean	Std. Deviation	Significance
No reflux	4	16.50	5.260	0.029
Grade II	18	16.67	5.445	
Grade III	54	21.07	6.771	
Total	76	19.79	6.658	

During analysis it was clearly significant that the healing time for ulcer in patients with SFJ reflux took a longer time as when compared to those who did not have the P value was 0.029

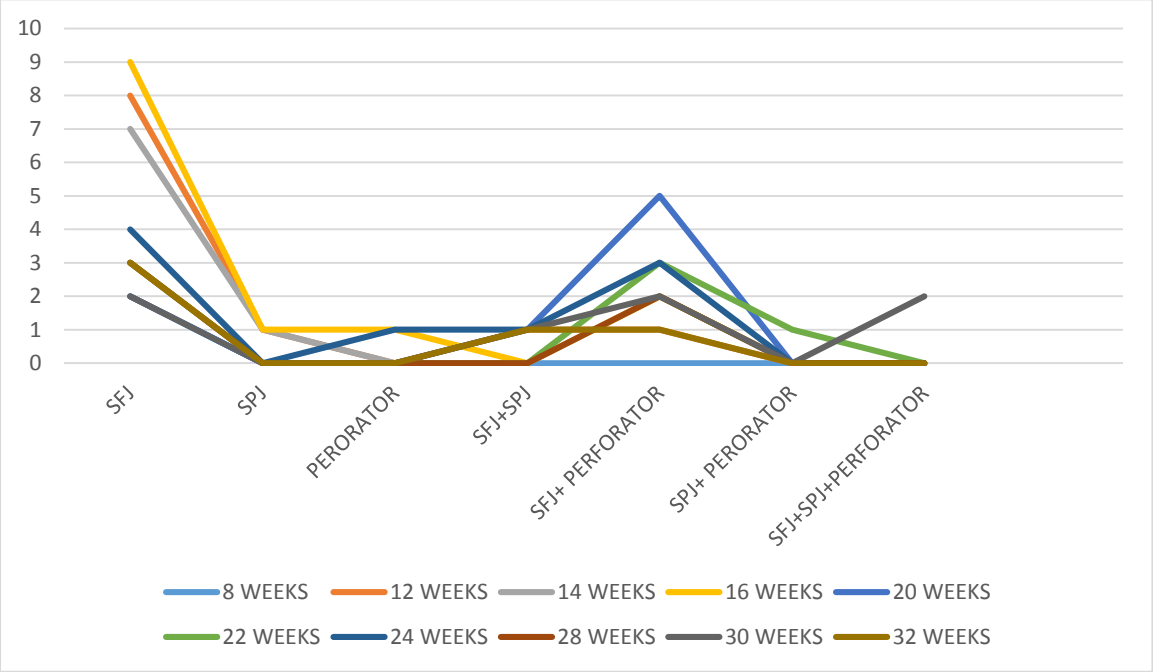
Multiple comparisons

Dependent Variable: Ulcer healing in weeks

Duplex Scan	Duplex Scan	Mean Difference	Std. Error	Significance
Normal	Grade II	-.17	3.553	.999
	Grade III	-4.57	3.331	.360
Grade II	Normal	.17	3.553	.999
	Grade III	-4.41(*)	1.750	.037
Grade III	Normal	4.57	3.331	.360
	Grade II	4.41(*)	1.750	.037

* The mean difference is significant at the .05 level.

The statistic also on multiple comparison between groups of patients who had no SFJ reflux and those who had Grade II and III reflux between them proved to be significant for those with Grade II and Grade III The P value was 0.037



We can observe that when proper treatment is instituted majority of ulcer heal by 16 weeks duration and the reason most commonly being reflux in the sapheno femoral junction.

SAPHENOPOPLITEAL JUNCTION REFLUX AND ULCER HEALING

	SPJ Reflux	N	Mean	Std. Deviation	Significance
Ulcer Healing in weeks	Positive	11	21.27	7.058	0.428
	Negative	65	19.54	6.612	

There was statistical significance to those patients who had SPJ reflux and their ulcer healing

PERFORATOR REFLUX AND ULCER HEALING

	Perforator	N	Mean	Std. Deviation	Significance
Ulcer Healing in weeks	Positive	27	22.52	5.646	.007
	Negative	49	18.29	6.745	

The patients who had reflux in perforators had a very significant influence on the ulcer healing time. The P value was 0.007

DISCUSSION:

Though there have been number of studies on the contributors to skin change and ulcer formation, there has been no consensus on the exact anatomic site which

is the culprit in the duration of ulcer healing. In this study we here by observe that majority of the patients 69. 6 % belonged to the age group of 40-59. Men are more affected 92 % as when compared to women. Right lower 48% limb slightly predominates left 40 %

The patients have recalcitrant ulcer ranging from 12- 38 weeks duration peeks between 20-22 weeks

On duplex the SFJ reflux 56.5 % dominated followed by the SFJ along with perforators 28.9 %

Most common anatomic presentation was incompetence in the SFJ (grade II reflux 69. 7% dominates over grade III 30.3%).

Among perforator's leg perforators are most common site to have reflux followed by leg with thighs and then leg with ankle and ankle alone.

Both sexes the approximate healing time following treatment is 16 weeks

CEAP 4 heals earlier then its counterparts approximately by 12 weeks followed by CEAP 5 which takes 22 weeks and then CEAP 6 which takes 28-30 weeks' time.

Finally The SFJ are the first to heal majority heal by 16 weeks

When two component is present it takes minimum of 12 weeks to maximum of 32 weeks When all three the SFJ, SPJ and Perforator are present it takes the maximum time of around 30 weeks to heal.

CONCLUSION

This study clearly suggest that as far as pigmentation and ulceration are concerned the underlying pathophysiology and **reflux** in the **SAPHENOFEMORAL JUNCTION and PERFORATOR** are more harmful and if left untreated take longer time to heal. They are statistically significant with the p value being **0.029 and .007** for saphenofemoral junction and perforator reflux respectively. As ever, the reality is more complicated as there is much still to be discovered as in this study the sample size was small and more number of cases will be needed for precious conclusions. In the meantime a working knowledge of the underlying process can help these ulcer patients heal faster

BIBILOGRAPHY

1. R. Rutherford's Vascular Surgery- 7th Edition.
2. Sabiston Textbook of Surgery: The Biological Basis of Modern Surgical Practice, 19th Edition
3. Duplex ultrasonography scanning for chronicvenous disease: Patterns of venous reflux Kenneth A. Myers, FRACS, Robert W. Ziegenbein, MSc, Ge Hua Zeng, MD and P. Geoffrey Matthews, Melbourne, Australia
4. Venous ulcers of the lower limb: Where do we stand?Chatterjee SS.Indian J Plast Surg. 2012 May
   (PubMed review)
5. Duplexsonography investigation in patients with venous ulcer.[Article in German]Jeanneret-Gris (PubMed review)
6. Prolonged healing of venous leg ulcers: the role of venous reflux, ulcer characteristics and mobility. Hjerppe A, Saarinen JP, Venermo MA, Huhtala HS, Vaalasti A. (PubMed review)
7. Identifying the source of superficial reflux in venous leg ulcers using duplex ultrasound. Obermayer A, Garzon K.(PubMed review)
8. Current concepts in chronic venous ulceration. Tassiopoulos AK, Golts E, Oh DS, Labropoulos N. (PubMed review)
9. Handbook of venous disorder, third edition, peter Golvizki, Micheal.C.Dalsing, Elkof, L.Montea, Gregoryy, Thomas W wakefield

10.Beldon P (2009) Bandaging: which bandage to use and when. Wound Essentials 4: 52-61

11.DowsettC (2011) Treatment and prevention of recurrence of venous leg ulcers using RAL hosiery. Wounds UK 7(1): 115-19

12.Kistner R (2010) Emerging treatment options for venous ulceration in today's wound care practice. Ostomy Wound Manage 56: 3-4

13.Lindsey E (2001) Compliance with science: benefits of developing community leg clubs. Br J Nurs 10(22): S66-74

14.NHS Centre for Reviews and Dissemination. (1997) Compression therapy for venous leg ulcers. Effective Health Care 3(4): 1-12

15. RCN (2006) Clinical Practice Guidelines. RCN, London

16.Stephen-Haynes J (2011) How to... Top ten tips for Doppler ABPI. Wounds International 2(4)

17.SIGN (2010) Management of Chronic Venous Leg Ulcers. A National Clinical Guideline. SIGN, Edinburgh

18.VowdenP, Apelqvist J, Moffatt C (2008) EWMA Position Document. Hard-to-heal wounds: a holistic approach. MEP, London

19.WUWHS (2008) Principles of Best Practice: Compression in venous leg ulcers. A consensus document. MEP Ltd, London

20.NCBI,Pubmed .gov websource

20. FromWikipedia, the free encyclopedia web source

21. Chocrane library websource

ABBREVIATIONS

CT- Computerized Tomography

CVI Chronic venous insufficiency

Hg - Mercury

IVUS- intravenous Ultrasound

mm- millimeter

MMP- Matrix metallo proteinases

MRV- Magnetic resconance venography

ms meter per sec

N - Mean

Pr- perforator

Sd- Standard deviation

SFJ - Saphenofemoral junction

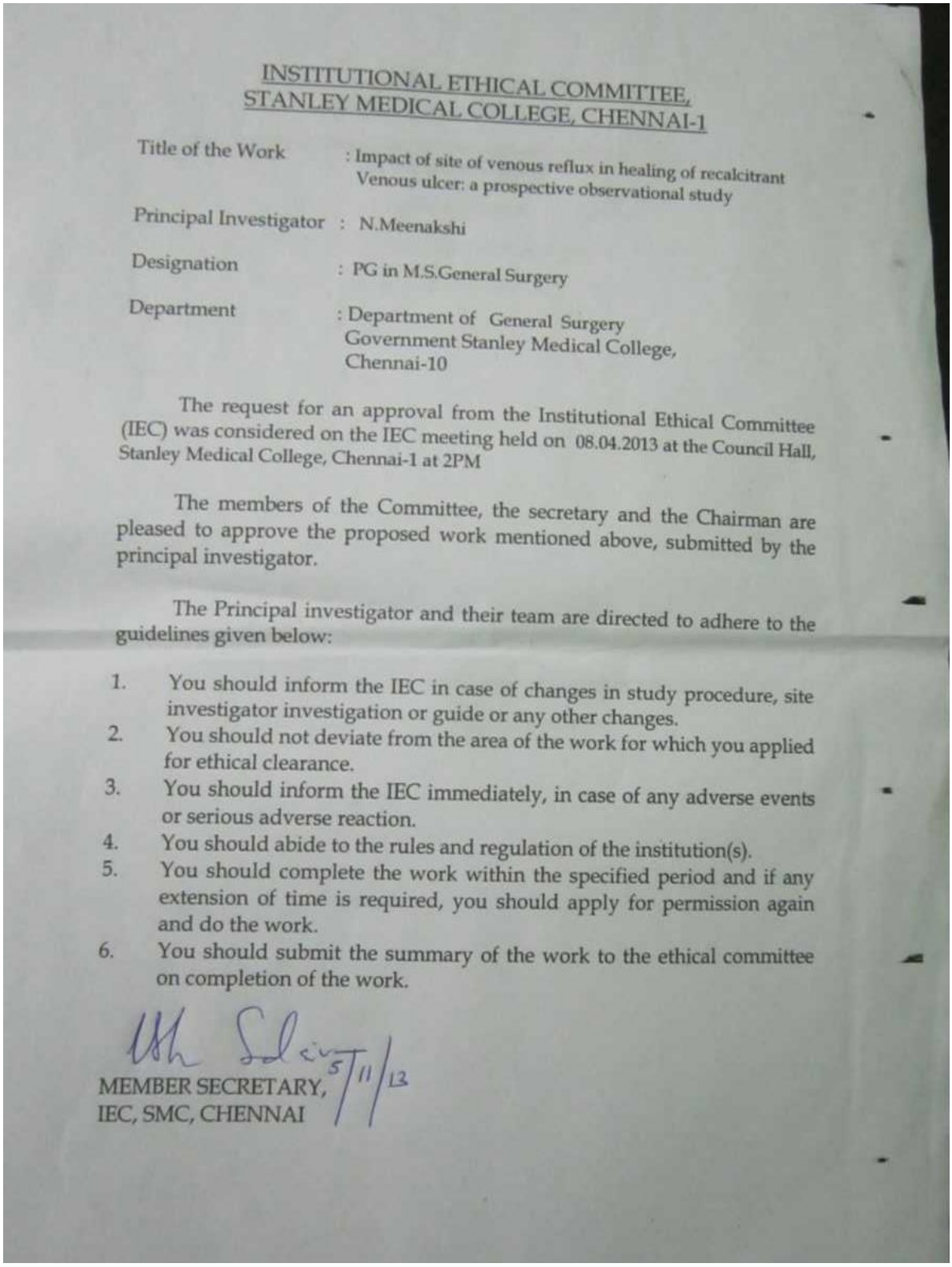
Sig- Significance

SPJ- Saphenopopliteal junction

USG- ultrasonogram

ANNEXURES

ETHICAL COMMITTEE APPROVAL FORM



INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Impact of site of venous reflux in healing of recalcitrant Venous ulcer: a prospective observational study

Principal Investigator : N.Meenakshi

Designation : PG in M.S.General Surgery

Department : Department of General Surgery
Government Stanley Medical College,
Chennai-10

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 08.04.2013 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

5/11/13

MEMBER SECRETARY,
IEC, SMC, CHENNAI

PROFORMA

Case No:

Name: Age:

Sex:

I.P. NO:

Occupation:

Address:

Contact No:

Date of admission:

Date of discharge:

Presenting history: Duration onset:

Dilated tortuous veins

Pain

Edema legs

Skin discoloration

Ulcer

Past history

H/O trauma Y/N
H/O previous surgery Y/N
H/O prolong immobilization Y/N
H/O previous DVT Y/N
H/O DM/HT/ PTB Y/N
H/o drug intake Y/N

Family History of varicose veins Y/N

Treatment History:
Pervious surgery for varicose veins Y/N
Conservative modality tried Y/N

Smoker Y/N

General Examination:

BMI - CVS:

PR - RS:

BP - P/A:

Local Examination:

Limb involved - Right / left
CEAP
Ulcer - Size -
Site -
Edge -
Floor -
Surrounding skin-
Thickness
Granulation tissue-

Peripheralpulses -

INVESTIGATIONS:

Hb%
TC
DC
ESR
Blood - Urea
Sugar
Sr. creatinine
CRP

Biopsy

CHEST X RAY

ECG

DUPLEX SCAN:

SFJ reflux - Y/NGrade -
SPJ reflux - Y/N
Perforators - Sites Reflux

Deep vein status -Reflux/ thrombus

Segment

MANAGEMENT:

Multilayered compression

bandage

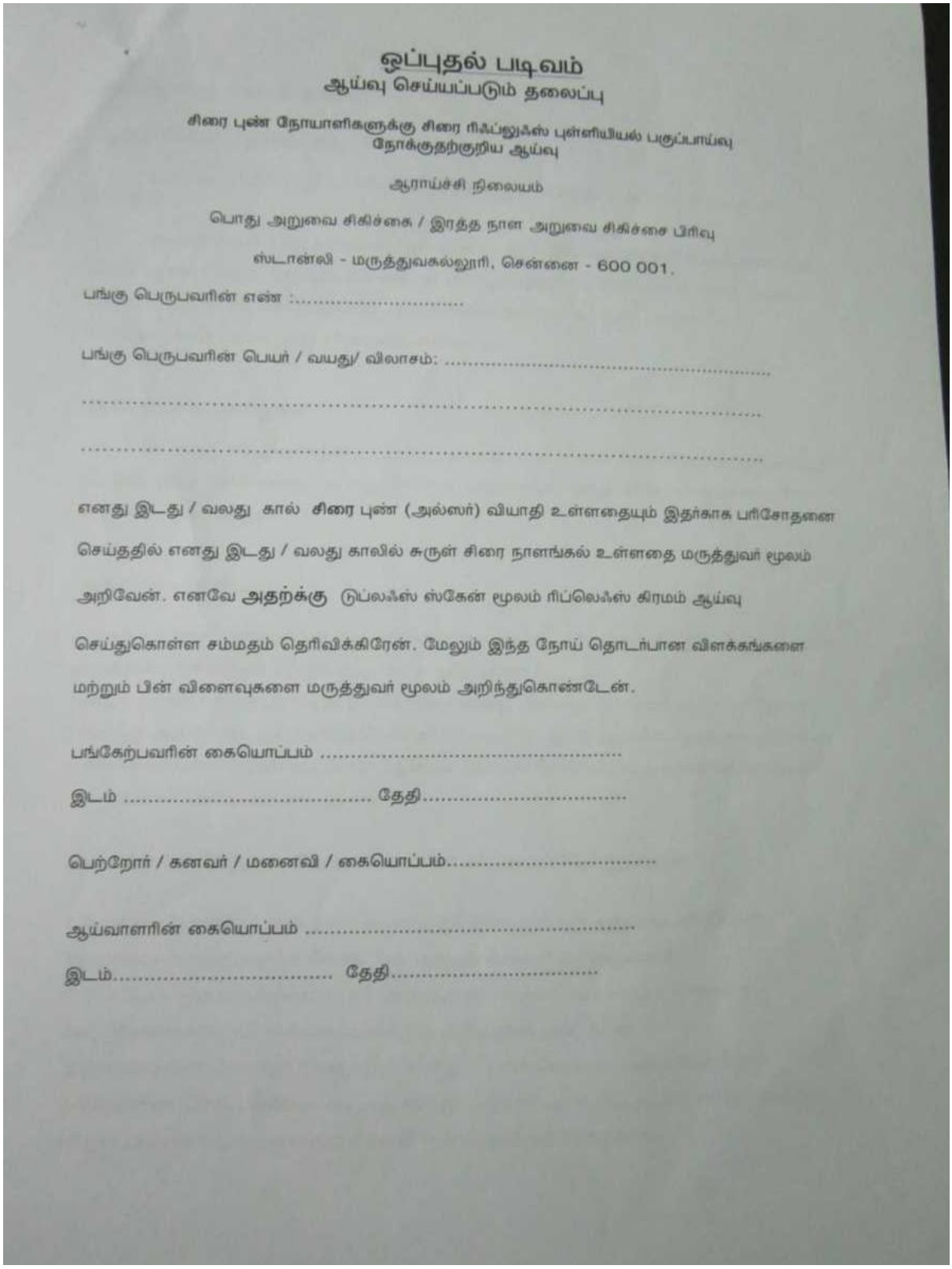
Surgery

Endovenous surgery - EVLT/RFA/foam Sclerotherapy

FOLLOW UP:

	Immediate Post Op	3 week	1month	3 months	6 months	12months
ULCER SIZE						
GRANULATION						
RECCURANCE						

INFORMED CONSENT FORM



ஒப்புதல் படிவம்
ஆய்வு செய்யப்படும் தலைப்பு

சிரை புண் நோயாளிகளுக்கு சிரை ரிஃப்லுஃஸ் புள்ளியியல் பகுப்பாய்வு நோக்குதற்குறிய ஆய்வு

ஆராய்ச்சி நிலையம்

பொது அறுவை சிகிச்சை / இரத்த நாள அறுவை சிகிச்சை பிரிவு

ஸ்டான்லி - மருத்துவகல்லூரி, சென்னை - 600 001.

பங்கு பெருபவரின் எண் :.....

பங்கு பெருபவரின் பெயர் / வயது/ விலாசம்: .....

.....

.....

எனது இடது / வலது கால் சிரை புண் (அல்ஸர்) வியாதி உள்ளதையும் இதர்காக பரிசோதனை செய்ததில் எனது இடது / வலது காலில் சுருள் சிரை நாளங்கல் உள்ளதை மருத்துவர் மூலம் அறிவேன். எனவே அதற்க்கு டுப்லஃஸ் ஸ்கேன் மூலம் ரிப்லெஃஸ் கிரமம் ஆய்வு செய்துகொள்ள சம்மதம் தெரிவிக்கிரேன். மேலும் இந்த நோய் தொடர்பான விளக்கங்களை மற்றும் பின் விளைவுகளை மருத்துவர் மூலம் அறிந்துகொண்டேன்.

பங்கேற்பவரின் கையொப்பம் .....

இடம் ..... தேதி.....

பெற்றோர் / கனவர் / மனைவி / கையொப்பம்.....

ஆய்வாளரின் கையொப்பம் .....

இடம்..... தேதி.....

PATIENT INFORMATION BROUCHER

நோயாளி தகவல் தாள்

நோயாளிகளுக்கான தகவல்:

ஆரய்ச்சியின் நோக்கமும், பயன்களும்,

உங்கள் பங்கேற்பு திட்டமிடப்பட்டுள்ள இந்த மருத்துவ ஆராய்ச்சி ஆய்வின் நோக்கம்:

காலில் சுருள் சிரை நாளங்கள் / சிரை புண் - ஐ டுப்லஃஸ் ஸ்கேன் மூலம் ரிப்லெஃஸ் கிரமம் ஆய்வு செய்து நோயின் தன்மையை அறிந்து அறுவை சிகிச்சை அல்லது லேசர் சிகிச்சை மூலம் சரி செய்வதினால், வியாதியின் தன்மை மற்றும் அதற்கு உரிய சிகிச்சை மூலம் புண் விரைவாக குணமாகும்

ஆய்வு நடைமுறைகள்

20 முதல் 80 வயதிற்குள் உட்ப்பட்ட வியாதியுடன் உள்ள ஆண் / பெண் நோயாளிகள் மட்டுமே இந்த சிகிச்சைக்கு சேர்த்துக்கொள்ளப்படுவார்கள். இந்த பரிசோதனையானது 12 மாதங்கள் நடைபெறும்.

அந்தரங்கத்தன்மை

உங்கள் / உங்கள் பிள்ளையின் / உறவினரின் மருத்துவ பதிவேடுகள் மிகவும் அந்த்தரங்கமாக வைத்துகொள்ளப்படும் மற்றும் மற்ற பிற மருத்துவர்கள் / விஞ்ஞானிகள் / இந்த ஆய்வின் தணிக்கையாளர்கள் அல்லது ஆராய்ச்சி ஆதரவாளர்களின் பிரதிநிதி ஆகியோரிடமும் அவை வெளிப்படுத்தப்படும். இந்த ஆய்வின் முடிவுகள் அறிவியல் பத்திரிகைக்களில் பிரசுரிக்கபடலாம். ஆனால், பெயரை வெளியிடுவது மூலம் நோயாளிகள் அடையாளம் காட்டப்படமாட்டர்கள்.

ஆய்வில் பங்கேற்கும் நோயாளிகளின் கடமைப் பொறுப்புகள்

உங்களை / உங்கள் உறவினரை கவனித்துகொள்ளும் மருத்துவருடன் நீங்கள் முழுமையாக ஒத்துழைக்க வேண்டும், மற்றும் உங்கள் மருத்துவரால் குறிப்பிடப்படும் மருந்துகளை தர அனுமதிக்க வேண்டும் என்று உங்களைக் கேட்டுகொள்கிறோம். சிகிச்சையளிக்கும் மருத்துவர் அளிக்கும் அறிவுரைகளை பின்பற்ற வேண்டும் என்றும் , என்னென்ன செய்யவேண்டும், என்னென்ன செய்ய செய்யக்கூடாது என்று உங்களிடம் கூறப்பட்டுள்ளவற்றிலிருந்து சற்றும் விலகக்கூடாது என்றும் நீங்கள் எதிர்ப்பார்க்கப்படுகிறீர்கள்.

ஆய்வில் உங்கள் பங்கேற்பு மற்றும் உங்க ள் உரிமைகள்

இந்த ஆய்வில் உங்கள் / உங்கள் உறவினரின் பங்கேற்பு தன்னிச்சையானது மற்றும் காரணங்கள் எதையும் கூறாமலேயே நீங்கள் / உங்கள் உறவினர் இந்த ஆய்விலிருந்து எந்த ஒரு நேரத்திலும் விலகிக் கொள்ளலாம். எப்படியிருந்தாலும், உங்கள் / உங்கள் உறவினரின் உடல் நிலைக்கேற்ப உங்களுக்கு / உங்கள் உறவினருக்கு பொருத்தமான சிகிச்சை அளிக்கப்படும். ஆய்வில் பங்கேற்க நீங்கள் மறுப்பதால், அடுத்து வரும் ஆராய்ச்சி ஆய்வுகளில் உங்களை / உங்கள் உறவினர் பங்கேற்பை மறுப்பது போன்ற எந்த வித அபராதமும் விதிக்கப்படாது. உங்களை / உங்கள் உறவினரை கவனித்துக் கொள்ளும் மருத்துவருடன் முழுமையாக ஒத்துழைக்க நீங்கள் சம்மதிக்க வேண்டும். எந்த ஒரு நேரத்திலும், நீங்கள் மோசமாக உணர்ந்தாலோ அல்லது வேறு ஏதேனும் உடல் நலக்குறைவு உண்டானாலோ, தயவு செய்து, உங்களை / உங்கள் கவனித்து வரும் மருத்துவரிடம் உடனடியாக தெரிவிக்கவும். சிகிச்சை உங்களுக்கு பொருத்தமாக இருக்காது என்று தோன்றினால் உடனடியாக நிறுத்தப்படும். உங்கள் / உங்கள் சம்மதம் இன்றியே கூட ஆய்வு நிருத்தபடுவது சாத்தியமே.

நாள்:

நோயாளியின் கையொப்பம் /

இடது பெருவிரல் ரேகை
(மருத்துவரால் படித்துக்காட்டப்பட்டது)

S.No	NAME	AGE	SEX	IP.NO	LIMB SIDE	ULCER DURATION BEFORE TREATMENT	CEAP CLASSIFICATION	DUPLEX SCAN				MANAGEMENT	ULCER HEALING TIME/ SKIN COLOUR CHANGE
								SFJ REFLUX/ GRADE	SPJ REFLUX	PERFORATOR REFLUX/ SITE	DEEP VENUS RFLUX/ OBSTRUCTION		
1	ELUMALAI	50	M	58490/12	R	12	5	+/III	-	-	-	EVLT	16 WEEKS
2	ANNADURAI	42	M	54801/12	R	14	4	+/III	-	+/LEG	-	SURGERY	12 WEEKS
3	DHINAKARAN	32	M	55755/12	L	14	4	+/II	-	-	-	RFA	8 WEEKS
4	ANBU	27	M	53492/12	R/REC	24	6	-	+	-	-	SURGERY	16 WEEKS
5	SHIVASHANKAR	61	M	53517/12	R	30	5	+/II	-	-	-	EVLT	12 WEEKS
6	PRAKASH	32	M	51470/12	R	20	5	+/III	-	-	-	EVLT	8 WEEKS
7	PREMKUMAR	20	M	53498/12	R	22	4	+/II	-	-	-	SURGERY	14 WEEKS
8	GOVINDAMMAL	55	F	53498/12	B/L-R	12	5	+/III	-	+/ANKLE	-	SURGERY	16 WEEKS
9	SAIPRAKASH	22	M	53125/12	B/L-L	14	4	+/II	-	-	-	SURGERY	14 WEEKS
10	RAMASUBBU	52	M	53531/12	L	20	6	+/III	-	+/LEG	-	SURGERY	20 WEEKS
11	RAMASAMY	48	M	53524/12	R	24	5	+/III	-	+/LEG	-	SURGERY	14 WEEKS
12	RAJAVEL	45	M	55525/12	L	16	5	+/III	-	-	-	SURGERY	16 WEEKS
13	SEEMAN	32	M	63793/12	L	18	4	+/III	-	-	-	SURGERY	12 WEEKS
14	JAYARAMAN	55	M	54407/12	R	22	5	+/III	-	-	-	SURGERY	16 WEEKS
15	MAHADEVI	40	F	55556/12	B/L-L	14	5	+/III	-	+/LEG	-	SURGERY	20 WEEKS
16	BASKAR	40	M	55689/12	R	20	5	+/III	-	+/LEG	-	SURGERY	20 WEEKS
17	MUNI	41	M	57641/12	L	22	6	+/III	-	+/thigh/LEG	-	SURGERY	24 WEEKS
18	NAGARAJ	46	M	2965/13	L	20	4	+/III	-	-	-	EVLT	12 WEEKS
19	IRUDYARAJ	56	M	2552/13	L	16	4	+/II	-	-	-	EVLT	12 WEEKS
20	SHEKAR	50	M	6040/13	L	30	5	+/III	-	-	-	SURGERY	16 WEEKS
21	KRISHNAMOORTHY	46	M	5328/13	R	18	5	+/III	-	-	-	SURGERY	14 WEEKS
22	PANDURANGAN	53	M	7364/13	L	20	6	+/III	-	-	-	SURGERY	12 WEEKS
23	PONNIYAN	65	M	3551/13	R	26	6	+/III	-	-	-	SURGERY	24 WEEKS
24	SIVASANKAR	31	M	2982/13	L	14	4	+/II	-	-	-	SURGERY	16 WEEKS
25	VELU	44	M	5989/13	R	30	5	-	+	+/LEG/ANKLE	-	SURGERY	22 WEEKS
26	KENNEDY	48	M	6172/13	R	32	6	+/III	+	+/LEG	-	SURGERY	24 WEEKS
27	SHANKAR	35	M	2038/13	R	12	4	+/II	-	-	-	EVLT	12 WEEKS
28	VIJAYARAJAN	46	M	10471/13	R	14	5	+/III	-	-	-	SURGERY	24 WEEKS
29	SUNDARAM	68	M	8068/13	R	12	4	+/II	-	+/LEG/ANKLE	-	SURGERY	20 WEEKS
30	NAGARAJ	46	M	2965/13	L	16	4	+/II	-	-	-	EVLT	16 WEEKS
31	MD.RIYAZ	28	M	9804/13	R	14	4	+/II	-	-	-	SURGERY	24 WEEKS
32	SHERIF	40	M	8723/13	R	20	5	+/III	-	-	-	RFA	22 WEEKS
33	SHANMUGAM	57	M	7587/13	R	24	6	+/III	+	+/LEG/ANKLE	-	SURGERY	30 WEEKS
34	ANANDRAJ	55	M	7241/13	R	30	6	+/III	-	+/LEG	-	RFA	28 WEEKS
35	ELONGAVAN	45	M	8822/13	R	24	6	+/III	-	-	-	RFA	28 WEEKS
36	SEKAR	38	M	10291/13	L	18	4	+/III	-	-	-	SURGERY	14 WEEKS
37	NAGARAJ	45	M	14378/13	L	24	5	+/III	-	-	-	SURGERY	22 WEEKS
38	BASKAR	52	M	15954/13	R	18	5	+/III	-	+/LEG	-	SURGERY	30 WEEKS

39	VELU	52	M	15252/13	L	22	6	+/III	-	-	-	SURGERY	32 WEEKS
40	NAGAN	50	M	16414/13	L	24	6	+/III	+	+/LEG	-	SURGERY	30 WEEKS
41	BABU	50	M	16256/13	B/L- L	28	6	+/III	-	+/LEG	-	SURGERY	28 WEEKS
42	BALASUBRAMANI	40	M	16303/13	L	20	4	+/II	+	-	-	SURGERY	24 WEEKS
43	VIJAYARAM	47	M	17192/13	B/L-L	22	5	+/III	-	+/LEG	-	RFA	22 WEEKS
44	KANNAN	59	M	11263/13	R	30	6	+/III	-	-	-	RFA	28 WEEKS
45	SELVARAJ	48	M	13970/13	R	14	4	+/II	-	-	-	RFA	20 WEEKS
46	SHEIKSHAMEEN	38	F	16438/13	L	12	4	+/III	-	+/LEG	-	RFA	20 WEEKS
47	ELUMALAI	44	M	18106/13	B/L-BL	16	5	+/III	-	-	-	SURGERY	30 WEEKS
48	PARASAKTHI	49	F	17729/13	L	12	4	-	+	-	-	SP LIGATION	14 WEEKS
49	RADHAKRISHNAN	65	M	17952/13	L	18	5	+/III	-	+/LEG	-	SURGERY	22 WEEKS
50	LOGU	52	M	19889/13	L	14	4	+/II	-	-	-	SURGERY	12 WEEKS
51	PARTHIBAN	21	M	21165/13	L/REC	14	4	-	-	+/LEG/ANKLE	-	SURGERY	24 WEEKS
52	SYED	30	M	19917/13	L	18	4	+/III	-	+/LEG	-	SURGERY	14 WEEKS
53	RAMASAMY	46	M	21485/13	R	22	5	+/III	-	+/LEG	-	SURGERY	24 WEEKS
54	MURUGESAN	31	M	22171/13	L	12	4	+/III	-	-	-	SURGERY	14 WEEKS
55	SHANKAR	37	M	23627/13	R	38	6	+/III	-	-	-	SURGERY	30 WEEKS
56	VIJAYA	46	F	22900/13	R	16	4	+/II	-	-	-	SURGERY	14 WEEKS
57	NITYANANDAM	48	M	22284/13	L	20	5	+/III	-	-	-	EVLT	24 WEEKS
58	NARASIMHAN	37	M	25011/13	R	22	4	+/III	-	-	-	SURGERY	16 WEEKS
59	KALAVATHY	47	F	22013/13	R	12	4	-	+	-	-	SURGERY	12 WEEKS
60	VELMURUGAN	44	M	25947/13	R	28	6	+/III	-	-	-	SURGERY	32 WEEKS
61	BABU	42	M	25628/13	R	22	4	+/III	+	-	-	SURGERY	12 WEEKS
62	KASINATHAN	57	M	27327/13	R	24	6	+/III	-	+/LEG/ANKLE	-	RFA	28 WEEKS
63	PATCHAIPPAN	60	M	25877/13	R	28	6	+/III	-	+/thigh/LEG	-	SURGERY	30 WEEKS
64	RAVI	52	M	26892/13	L	24	5	+/III	-	-	-	RFA	16 WEEKS
65	VENKATESAN	50	M	26888/13	L	20	5	+/III	-	-	-	RFA	20 WEEKS
66	SUDHAKAR	30	M	26862/13	L	14	4	+/III	-	+/ANKLE	-	SURGERY	16 WEEKS
67	MURUGESAN	60	M	27276/13	L	22	6	+/II	+	-	-	SURGERY	30 WEEKS
68	DAYALAN	51	M	25686/13	R	20	6	+/III	-	-	-	RFA	32 WEEKS
69	ABDUL	27	M	28586/13	L	18	4	-	-	+/LEG/ANKLE	-	SURGERY	16 WEEKS
70	SURESH	40	M	28748/13	R	16	4	+/III	-	-	-	EVLT	14 WEEKS
71	MURUGAN	43	M	29389/13	L	22	5	+/III	-	+/LEG/ANKLE	-	SURGERY	32 WEEKS
72	DURAISAMY	52	M	28605/13	R	20	4	+/II	+	-	-	SURGERY	20 WEEKS
73	RAVI	52	M	31329/13	R	22	5	+/III	-	-	-	RFA	22 WEEKS
74	RAMESHBABU	45	M	30426/13	L	20	4	+/II	-	-	-	SURGERY	16 WEEKS
75	ABBAS	45	M	30289/13	R	22	4	+/III	-	-	-	SURGERY	12 WEEKS
76	BALAKRISHNAN	43	M	31013/13	L	28	5	+/III	-	+/LEG/ANKLE	-	RFA	22 WEEKS